

GOOD RISK ASSESSMENT PRACTICE IN HOSPITALS



This dissertation is submitted for the degree of Doctor of Philosophy

Gulsum Kubra Kaya
Girton College

University of Cambridge
Department of Engineering
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ABSTRACT

Good Risk Assessment Practice in Hospitals

Risk assessment is essential to ensure safety in hospitals. However, hospitals have paid little attention to risk assessment. Several problems have already been identified in the literature about current risk assessment practice, such as inadequate risk assessment guidance and bias in risk scoring.

This research aimed to improve current risk assessment practice in hospitals in the National Health Service (NHS) in England. To address this aim, the research investigated current risk assessment practice and designed a new risk assessment approach by the use of mixed methods. One hundred hospitals' risk assessment documents were reviewed to examine the current recommended risk assessment practice. Seventeen interviews and sixty-one questionnaires were conducted, a risk management system from a single hospital was reviewed, and strategic risks from thirty-four hospitals were reviewed, in order to examine how risks are assessed in actual practice. Following that, the proposed approach was designed by conducting requirements analysis and then evaluated by interviews and questionnaires with ten healthcare staff.

The findings of this research reveal that hospitals conduct risk assessments in different ways (i.e. with a focus on individual patient-based, operational and strategic risks). There are also many problems involved in current risk assessment practice regarding both the foundations and use of risk assessment. For example, organisation-wide risk assessments predominantly rely on risk matrices which might lead to wrong risk prioritisation and resource allocation; and risks tend to reflect existing or past problems rather than being proactive. All these reveal a need to improve current risk assessment practice.

This research makes an important contribution to the current understanding of risk assessment practice in hospitals by providing extensive evidence on both recommended and actual practice, and proposes a new risk assessment framework. The framework guides healthcare staff on how to conduct risk assessment in a more comprehensive way by encouraging its potential users to consider good risk assessment practice.

Gulsum Kubra Kaya

DECLARATION

This thesis is the result of my own work and includes nothing which is the outcome of work done in collaboration. Any reference to the work of other researchers is clearly indicated in the text. This thesis has not been submitted in whole or in part for consideration for any other degree or qualification at this University or any other Institute of Learning. This thesis does not exceed 65,000 words, including appendices, bibliography and tables, and does not contain more than 150 figures.

Gulsum Kubra Kaya
Girton College
Cambridge University
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ABBREVIATIONS

ALARP	As Low As Reasonably Practicable
BAF	Board Assurance Framework
CQC	Care Quality Commission
COSO	Committee of Sponsoring Organisations of the Treadway Commission
DoD	United States Department of Defence
DRM	Design Research Methodology
ETA	Event Tree Analysis
FAA	Federal Aviation Administration
FMEA	Failure Modes and Effects Analysis
FRAM	Functional Resonance Analysis Method
HAZOP	Hazard and Operability Study
HRA	Health Research Authority
HSE	Health and Safety Executive
ISO	International Organisation for Standardisation
NASA	The National Aeronautics and Space Administration
NICE	The National Institute for Health and Care Excellence
NHS	National Health Service
NHS LA	National Health Service Litigation Authority
NPSA	National Patient Safety Agency
PDSA	Plan Do Study Act
RAF	Risk Assessment Framework
REC	Research Ethics Committee
STAMP	Systems-Theoretic Accident Model and Processes
STPA	Systems-Theoretic Process Analysis

GLOSSARY

Adverse Event	Any event or circumstance leading to unintentional harm or suffering (NPSA 2007)
Board Assurance Framework (BAF)	The BAF provides a structure and process that enables the Trust to focus on the risks to achieving its most important (principal) annual objectives and be assured that adequate controls are operating to reduce these risks to acceptable levels (GGI 2009)
Complex System	A system that has many parts which interact each other, and that is difficult to understand.
Hazard	Source of potential harm (ISO 2009)
Risk	A potential undesired event that has effect(s) on objectives
Risk Assessment	Overall process of risk identification, risk analysis and risk evaluation (ISO 2009)
Risk Management	Coordinated activities to direct and control an organisation with regard to risk (ISO 2009)
Risk Rating/Level	Magnitude of a risk, which is measured by multiplying likelihood and consequence values
Risk Register	A database that holds the main record of all identified risks to the trust's objectives and operations (Aintree University Hospital NHS Foundation Trust)
Risk Score	The product of likelihood and consequence scores (typically 1 to 25) that are assigned to likelihood and consequence ratings
Safety	The minimisation of any undesired situations in the healthcare delivery system that may lead to a threat, harm or loss to any parts of that system
System	A combination of interacting elements organised to achieve stated purpose(s) (ISO 2008)
Tolerability	The degree of acceptability of a risk

CHAPTER 1

INTRODUCTION

1.1 RESEARCH MOTIVATION

Healthcare organisations deliver safe care to millions of patients every day (Woodward et al. 2004). However, there are also a number of patients that are exposed to harm. This could be due to the healthcare system being inherently risky (Leape et al. 1998) and error-prone (Hutchinson et al. 2015), as well as to a lack of application of effective safety interventions (Shojania and Thomas 2013).

Indeed, a large number of patients experience adverse events during their care delivery. In the world, approximately, 42.7 million patients are estimated to experience adverse events each year (Jha et al. 2013). Examples of the estimations of adverse event rate from a range of countries include:

- 25.1 percent of patient admissions in the USA, of which 84.4 percent lead to temporary harm, 2.9 percent to permanent harm, 8.5 percent to life-threatening situations and 2.4 percent to death (Landgrigan et al. 2010),
- 12.9 percent in New Zealand, of which 75 percent result in minor harm and 15 percent in permanent disability or death (Davis et al. 2002),

- 12 percent in Sweden, of which 70 percent were preventable with 88 percent resulting in temporary harms, 9 percent in permanent disability and 3 percent in death (Soop et al. 2009),
- 6.8 percent in Canada, of which 55.7 percent result in no or minor harm, 12.5 percent in temporary harm, 5.2 percent in permanent harm and 15.9 percent in death (Baker 2004),
- 10.8 percent in the UK, of which 66.4 percent lead to no or minor harm, 19.1 percent to temporary harm, 6.4 percent to permanent harm and 8.2 percent to death (Vincent et al. 2001).

To illustrate further patient safety related issues in the UK healthcare system, over 1 million people experience incidents each year in the National Health Service (NHS), of which 69.4% result in no harm to patients, 24% result in low harm (e.g. requiring minor treatment), 6% result in moderate harm (e.g. requiring further intervention) and 0.6% result in death or severe harm (e.g. causing permanent harm) (Davies 2014). Although these estimations may vary and the grounds for their reliability may be questionable due to the under-reporting of incidents and the measurement methods of adverse events rates (Shojania and Dixon-Woods 2016), the estimations given illustrate that experiencing adverse events is a widespread problem all over the world (Hutchinson et al. 2015; Thomas et al. 2000).

To reduce harm in healthcare, substantial attention has been paid to patient safety, especially in the last two decades (Hayes et al. 2014; Sujan et al. 2015; Vincent and Amalberti 2016). Some leading reports have been published to increase safety awareness, including *An organisation with a memory* (DoH 2000), *To err is human* (Kohn et al. 2000), and *Crossing the quality chasm* (IOM 2001). A number of research studies were conducted with the aim of reducing harm, including studies related to patient falls (Aranda-Gallardo et al. 2015; Lovallo et al. 2010), the mortality rate (Chou et al. 2015) and infections (Chandonnet et al. 2013). Sweeping reforms have been proposed in these reports, driven by safety-critical industries (e.g. nuclear, aviation and defense), such as the implementation of incident and risk reporting systems (Mitchell et al. 2016; NHS England 2015b).

Yet, safety interventions in the healthcare industry have been found to have a limited effect on patient safety (Dixon-Woods and Pronovost 2016; Dückers et al. 2009; Hudson et al. 2012; Sujan et al. 2016).

In healthcare, safety interventions have paid more attention to the investigation of harm, rather than focusing on ways to minimise harm before it occurs (Sujan et al. 2017; Ward et al. 2010). A risk-based approach could complement current reactive practice, which is through risk assessment as part of risk management. Yet, even risk assessment has its problems when it is in place. Eidesen *et al.* (2009) claim that many of the problems are in relation to the foundations and the use of risk assessment, such as how to express risk and how to use risk assessment as a tool to improve patient safety. In addition, the risk register systems tend to be used as bureaucratic data collection systems (Illingworth 2015a); responsibilities for safety concerns are diffused (Berwick et al. 2013); risk assessment techniques are not used much, and if used, they may be used without training (Card et al. 2012b; Ward et al. 2010); and insufficient risk evaluation guidance is provided (Card et al. 2013). All these indicate that there is great potential to improve current risk assessment practice.

1.2 RESEARCH AIMS

The overall aim of this research study is to improve current risk assessment practice in hospitals in NHS England. In particular, this research aims to design a better risk assessment approach in hospitals by learning from prescribed good risk assessment practice as well as from challenges in current practice.

1.3 RESEARCH SCOPE

The scope of this research is risk assessment that is applied to patient safety. Risk assessment is a part of risk management, and it consists of risk identification, risk analysis and risk evaluation steps.

The research focuses on risk assessment practice instead of focusing on risk management as a broader field. This is due to the fact that there have been many studies conducted regarding the reactive application of risk management by giving less attention to risk assessment. In addition, this study focuses on risk assessment in hospitals. Although patient safety related research studies have already dominated within hospital settings, the characteristics of hospitals as being complex, employing a large number of healthcare staff, having the highest healthcare spending, and experiencing an enormous number of incidents still make hospitals an attractive setting in which to conduct research (Davies 2014; Vincent and Amalberti 2016). Thus, this research also focuses on improving safety in hospitals, particularly hospitals in NHS England since the researcher is based in England.

1.4 THESIS STRUCTURE

Figure 1.1 presents the structure of this thesis. The thesis contains eight chapters. Each chapter is summarised below:

Chapter 1: Introduction

This chapter introduces the underlying motivation, aims, scope and thesis structure.

Chapter 2: A Literature Review for Risk Assessment

This chapter presents an overview of the research topic, explains good risk assessment practice, addresses gaps in the literature, highlights areas for further research and sets research questions for investigation.

Chapter 3: Research Process

This chapter introduces the research process followed in this research by outlining the research paradigm, research questions, research methodologies, research design and research methods.

Chapter 4: Recommended Risk Assessment Practice in Hospitals in the NHS England

This chapter investigates current recommended risk assessment practice, ‘*work as described*’, through the analysis of hospitals’ risk assessment policies and procedures.

Chapter 5: Actual Risk Assessment Practice in Hospitals in the NHS England

This chapter further investigates the actual risk assessment practice, ‘*work as done*’, through conducting interviews and questionnaires as well as analysing a risk management system and Board Assurance Frameworks (BAF).

Chapter 6: Proposed Risk Assessment Approach

This chapter proposes a new risk assessment approach through the design of a Risk Assessment Framework (RAF). It is designed by learning from good risk assessment practices prescribed in safety-critical industries and by addressing existing challenges within current risk assessment practice in hospitals.

Chapter 7: Evaluation of the Proposed Risk Assessment Approach

This chapter presents the results of an initial evaluation of the proposed risk assessment approach through conducting a case study, interviews and questionnaire.

Chapter 8: Conclusion

This chapter presents a brief response to each research question, discusses the contributions of this research and outlines potential further works.

1.5 SUMMARY

This chapter has presented an overview of this thesis. This research took its motivation from the need to improve safety in hospitals with a potential improvement area being identified as risk assessment. Finally, this chapter has introduced the structure of this thesis, summarised in Figure 1.1.

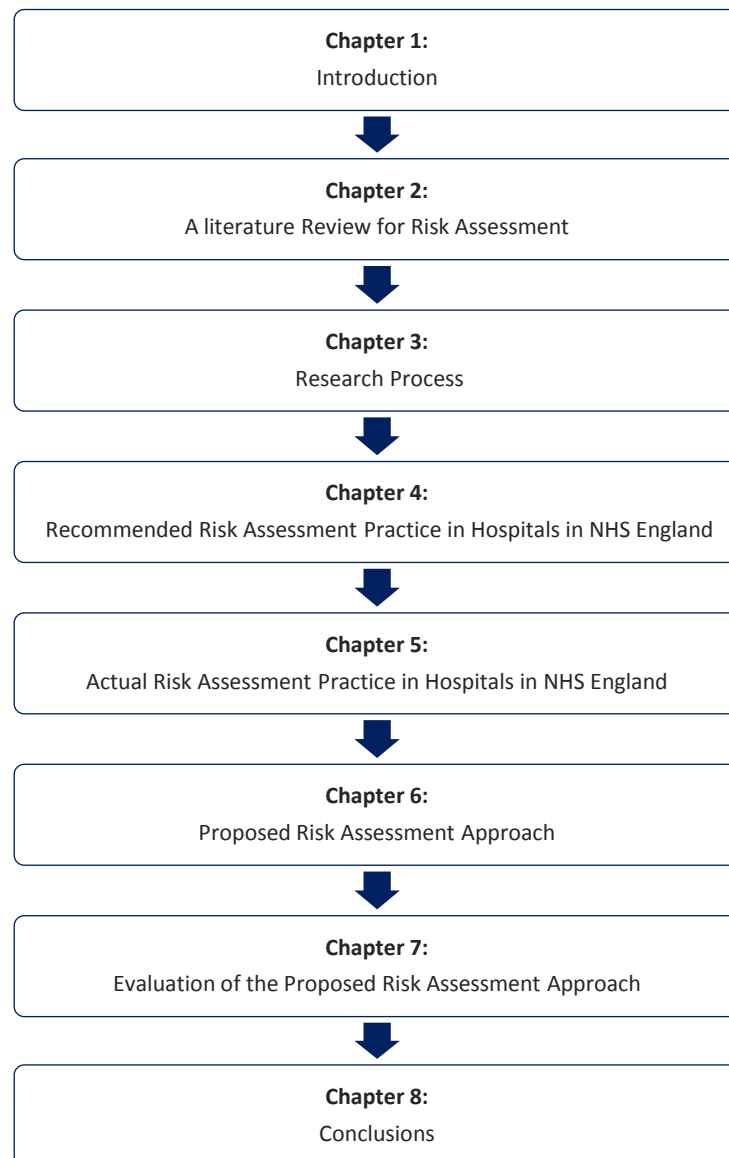


Figure 1.1 An overview of the thesis structure

CHAPTER 2

A LITERATURE REVIEW FOR RISK ASSESSMENT

2.1 INTRODUCTION TO LITERATURE REVIEW

This chapter provides the background to the research topic. An overview of NHS England is presented to understand the system to be improved. Then, in order to understand the science behind risk assessment, more groundwork is laid down by explaining what safety is, how accidents occur and what is involved in risk assessment. Leading on from this, the healthcare literature is reviewed to describe hospital applications as well as their existing challenges. Additionally, good risk assessment is explained as a reference point to determine potential improvements by learning from a number of national and international risk assessment guidelines. Gaps in the literature and potential areas for improvements are then identified. Finally, in light of the findings set out in this review, the research questions are presented.

2.2 APPROACH TO LITERATURE REVIEW

The research subject '*risk assessment in hospitals*' falls under several different topics such as risk management, safety, patient safety and quality. To provide a comprehensive review of the research topic, a narrative review approach was taken.

Primary and secondary literature regarding safety and risk assessment has been explored by using a multitude of search criteria and terms. Numerous sources were reviewed including, books, journals, reports, standards and white papers to conduct this search. These sources were identified via several routes: electronic healthcare databases (namely, PubMed and EMBASE), electronic science databases (namely, Science Direct, the Wiley Online Library and Elsevier), the Google Scholar search engine, the Department of Health's and its partner organisations' (including the NPSA, and the Health Foundation) publications databases, the British Standards Online (BSOL) library, reference chasing, relevant journals and searching publications by key authors.

The search of the above corpora was conducted using key terms, including *accident models, adverse events, hazard, healthcare, hospitals, NHS England, patient safety, risk, risk assessment, risk management, and safety*.

A large number of papers were reviewed to provide a comprehensive understanding of risk assessment and its applications in hospitals. Several databases were used to search for a combination of key terms (e.g. 'risk assessment' AND ('hospital' OR 'healthcare')). Papers were first screened based on title and abstract, and their selection was made based on the relevance of the research subject. In addition, key journals and reports were searched to provide information on the state of the science on the research subject. Papers were excluded if they primarily focused on clinical interventions or technical applications of other industries as well as if they were in low quality in the explanations and evidence provided. Selected papers were then used to provide a comprehensive literature review of the research topic.

In addition to these selections, subscriptions were made to the relevant leading journals such as *British Medical Journal Quality and Safety*, *Journal of Patient Safety*, *Risk Analysis*, *Ergonomics*, *Journal of Risk Research*, and *Safety Science*. Furthermore, relevant LinkedIn groups (i.e. NHS Quality and Risk Managers) and Twitter accounts (i.e. NHS Improvement, Health Foundation and SRA-Risk Analysis) related to healthcare and safety-critical industries were followed and consulted to understand people's practical experience.

2.3 AN OVERVIEW OF HEALTHCARE IN ENGLAND

Healthcare is defined as “*care activities, services, management or supplies related to the health of an individual*” (BSI 2011a). The healthcare system involves organisations, people and activities (WHO 2009). Ferlie and Shorthell (2001) explain the healthcare system by dividing it into four levels. These are: (1) the individual patient, (2) care teams (e.g. practitioners and patient family members), (3) organisations (e.g. hospitals) and (4) the political and economic environment (e.g. suppliers and national authorities) (Ferlie and Shorthell 2001).

In the UK, the National Health Service (NHS) delivers health care. The NHS was established after the Second World War. Each of the UK's four countries has its own NHS which is financed mainly through taxation (Grosios et al. 2010). Therefore, it is the responsibility of NHS England to lead healthcare services in England (Davies 2014). NHS England deals with over 1 million patients every 36 hours with around 1.2 million staff and with an annual budget of around £101.3 billion (NHS 2016).

Figure 2.1 shows the different levels of involvement in the healthcare system. For instance, there are local health and care services in the centre of the healthcare system that include GP surgeries, hospitals, pharmacies and community groups; and there are local and national organisations that investigate the care delivered by the local healthcare services. Additionally, there are a number of other organisations that are part of the healthcare system. For instance, the

Department of Health shapes healthcare in England, the National Institute for Health and Care Excellence (NICE) provides guidance and advice to improve health and social care, and the Care Quality Commission (CQC) regulates health and social care (Grosios et al. 2010). Furthermore, the NHS Litigation Authority (NHS LA) manages negligence and other claims, and supports initiatives to improve safety (NHS LA 2017).

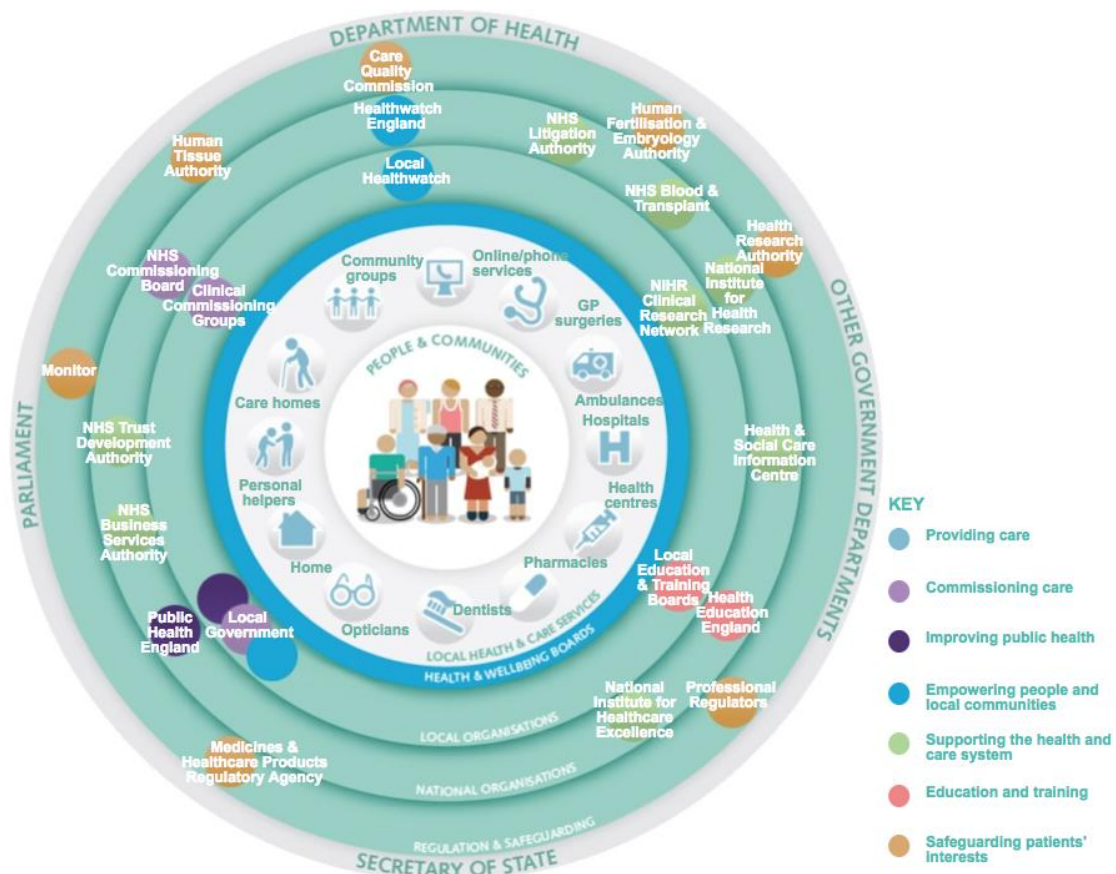


Figure 2.1 The health and care system in the UK DoH (2013)

In addition to the involvement of a large number of stakeholders in the delivery of healthcare system, each patient care delivery process is tailored to the needs of individual patients. Indeed, the healthcare system is complex, and healthcare delivery is difficult to achieve (Vincent and Amalberti 2016).

The difficulty of the healthcare delivery process has also been observed in the management of safety in healthcare. To deal with such a difficulty, engineering and management approaches have been implemented in healthcare

organisations (Cagliano et al. 2011; Clarkson et al. 2004; Carayon and Wood 2010). Particularly, safety in healthcare has evolved and developed in hospital contexts (Vincent and Amalberti 2016). This could be due to the fact that hospitals are complex, and hospitals have dominated healthcare spending and provision (Davies 2014).

As a result, progress has already been achieved on some issues (Illingworth 2015b; Vincent and Amalberti 2016). For instance, the percentage of patients surveyed receiving care free from pressure ulcers, falls, urine infections (in patients with a catheter) and venous thromboembolism increased by 3 percent between 2012 and 2015 (Illingworth 2015b). However, there is little evidence to demonstrate significant contributions of these safety applications to patient safety (Hudson et al. 2012; Sujan et al. 2016), and safety interventions have remained predominantly reactive (Dixon-Woods and Pronovost 2016; Dücker et al. 2009; Sujan et al. 2017). Thus, this research focuses on the proactive intervention of risk assessment to improve safety in hospitals.

Before moving on to the discussion of risk assessment, the safety context is explained in the following section.

2.4 UNDERSTANDING SAFETY

The literature provides a variety of definitions of safety. Some of these definitions are given below.

- The Oxford English Dictionary defines safety as *“the condition of being protected from or unlikely to cause danger, risk or injury”*,
- US Department of Defense identifies safety as, *“freedom from those conditions that can cause death, injury, occupational illness, or damage to or loss of equipment or property”* (DoD 1984),
- Hollnagel (2014b), who divides safety into Safety I and Safety II, identifies safety as *“nothing unwanted”* or *“the freedom from unacceptable risk”* as well as a situation in which *“as many things as possible go right”*.

Safety I focuses on *“What goes or went or could go wrong?”* by aiming at *“as few things as possible going wrong”*. Safety II focuses on *“How do things usually go right?”* by aiming at *“as many things as possible going right”* (Hollnagel et al. 2015). In so doing, while the Safety I aims to reduce the number of incidents by learning from extraordinary cases, the Safety II approach encourages learning from every day experience and adjusting performance to address changing demands (Hollnagel 2014b).

In the safety literature, the Safety I approach has been predominantly used in all industries. A large number of methods (e.g. FMEA, RCA and HAZOP) have been developed and successfully used based on this approach. In contrast, the Safety II approach has been used less, and few methods have been developed based on it, though one such method is FRAM (Functional Resonance Analysis Method) (Hollnagel 2004).

Hollnagel *et al.* (2015) explains that the need for the Safety II approach in healthcare is due to complexity and performance adjustments in everyday activities. Sujan *et al.* (2017) also highlights the value of the Safety II approach to learning from everyday experiences. Although the Safety II approach has a potential to minimise blame, since it focuses on success instead failure, it may still be reasonable to focus on negatives in healthcare for three primary reasons. First, there is little evidence to demonstrate that the applications of Safety II make systems safer than the applications of Safety I. Second, safety-critical industries (e.g. aviation and nuclear) are still successfully using the Safety I approach. Third, one argument Hollnagel (2014b) made to justify the Safety II approach was that accidents occur rarely, and, it is therefore easier to learn from every day successes. Although this might be true, not all incidents in healthcare occur rarely and most of them are repeat occurrences. This research, therefore, determines safety through adopting the Safety I approach, but while keeping in mind that there might be potential for the application of Safety II in some specific parts of the healthcare system.

In the healthcare literature, safety primarily focuses on patient safety from the perspective of Safety I (Sujan et al. 2017; DoH 2002; Hignett et al. 2016). Patient

safety is defined as *“the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare”* (Vincent 2010). Additionally, health and safety at work is another prioritised topic for safety in healthcare, one which is more advanced than patient safety (Card et al. 2012a; Ward et al. 2010). A health and safety at work act is defined as *“An act to make further provision for securing the health, safety and welfare of persons at work, for protecting others against risks to health or safety in connection with the activities of persons at work...”* (HM Government 1974). Based on the above safety descriptions, safety in healthcare can be defined as follows:

The minimisation of any undesired situations in the healthcare delivery system that may lead to a threat, harm or loss to any parts of that system.

While the definition above reflects the Safety I view, another definition can be provided from a Safety II perspective as follows:

The maximisation of all desired situations in the healthcare delivery system that may help to achieve success in any parts of that system.

To promote safety in healthcare, Vincent highlights that:

“Safety emerges from the interaction of the components of the system. It is more than the absence of adverse outcomes and it is more than avoidance of identifiable ‘preventable’ errors or occurrences. Safety does not reside in a person, device or department. Improving safety depends on learning how safety emerges from the interaction of components.” (Vincent 2010).

Thus, a safe system aims to minimise exposure to hazards and their impacts from the system, from its parts and from the interaction of these parts (Hollnagel 2008; Vincent 2010). Figure 2.2 explains this with the Safety I approach.

The healthcare delivery process impacts on the safety of both patients and healthcare staff. A hospital is considered to be a system, and many hazards may exist in this system, which could increase risks. There is also the possibility of

failures and errors in the system, which can lead to the occurrence of accidents. However, accidents and risks can be controlled to minimise the negative consequences. While risk assessment is a way to prevent harm before it occurs as well as to minimise it when it occurs, incident investigation aims to learn from the harm experienced. In order to learn from accidents and prepare a basis for risk assessment, accident models are used.

Accident models help understand the underlying causes of accidents so that, in turn, actions can be taken to prevent their reoccurrence or similar ones. In so doing, it is essential to understand the ways that failures and errors can lead to harm as well as the ways in which hazards can trigger risks in the system to be assessed.

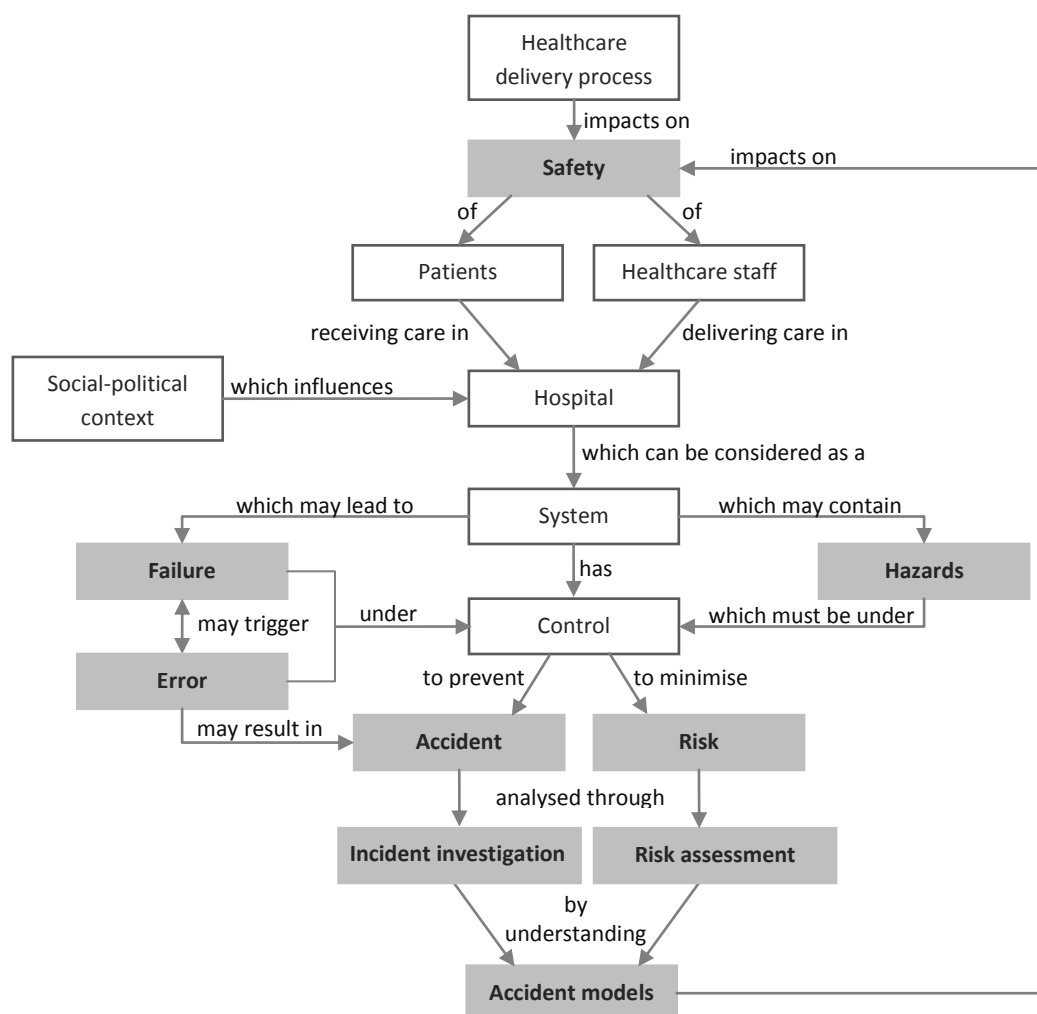


Figure 2.2 Potential influencing factors on safety in healthcare adapted from SIA (2012)

2.4.1 DEFINITIONS OF FAILURES AND ERRORS

2.4.1.1 Failures

A failure is defined as the “*termination of the ability of an item to perform a required function*” (BSI 2006). Failure(s) can be considered to be an outcome of an initial error, when the initial error is not recovered and its consequences are shifted (Woods et al. 2010). Figure 2.3 shows this relationship between failure and error.

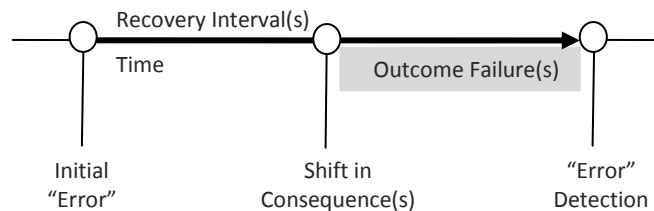


Figure 2.3 Relationship between error recovery and outcome failure adapted from Woods et al. (2010)

It is difficult to detect an error at the beginning, but detection becomes easier when the initial error leads to a failure. To illustrate this, an initial error, such as the poor maintenance of a medical device, might lead to malfunctioning of the medical device, and, then, to a service failure resulting in cancellation of patient appointments.

2.4.1.2 Errors

An error is defined by the Oxford English Dictionary as “*something incorrectly done through ignorance or inadvertence; a mistake, e.g. in calculation, judgement, speech, writing, action, etc.*” It is also defined as achieving a wrong or unintended action or the failure of a planned action (Aspden et al. 2006). Errors reveal symptoms about systems, organisations or technologies that should be investigated in depth (Hollnagel 1991; Rasmussen et al. 1987; Reason 1990). In addition, errors could contribute to accidents or near misses (Cagliano et al.

2011). However, this can be minimised by understanding the reason behind the errors.

In the healthcare context, a large number of errors occur, some of which lead to adverse events (Vincent et al. 2013). Of these, errors, in medication are a widely-discussed topic as this is estimated to be the major cause of harm (Choo et al. 2010). A medication error is identified as “*a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient*” (Ferner and Aronson 2006). Figure 2.4 shows the classification of medication errors based on a psychological approach.

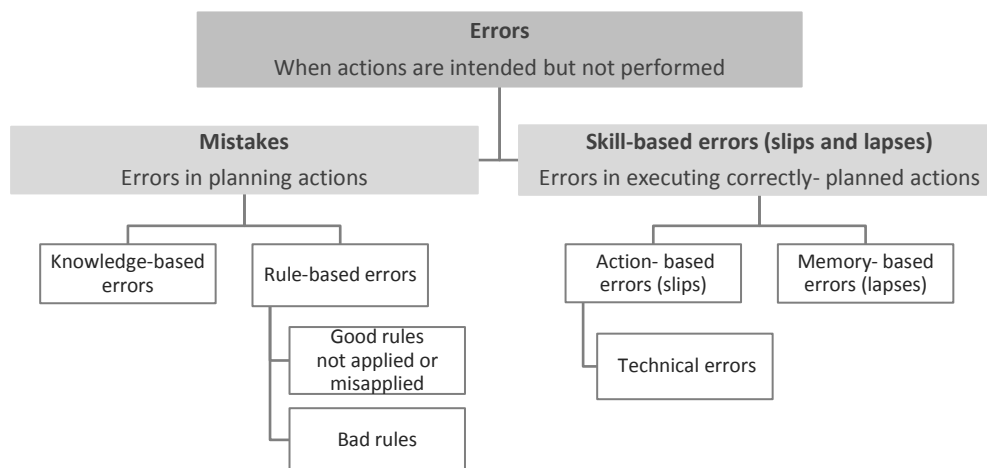


Figure 2.4 Classification of medication errors Ferner and Aronson (2006)

According to this approach, errors are divided into mistakes and skill-based errors. While mistakes are categorised into knowledge or rule based errors, skill-based errors are categorised into action or memory-based errors (Reason 1990). However, it is possible to prevent some of these errors. Reason (1990) recommends the improvement of knowledge to prevent knowledge-based errors, and the application of better rules to prevent mistakes caused by poor rules. In addition, Aronson (2009) suggests that staff training may reduce action-based errors, and checklists and computerised systems may eliminate memory-based errors.

Although some of the errors can be prevented, accidents may still occur in complex systems due to several contributing factors. In complex systems, the system is composed of many parts and it is difficult to understand the system as a whole. Vincent *et al.* (1988) identify seven factors that influence safety and quality of the clinical practice, which are (1) patient factors (e.g. personality and condition), (2) task and technology factors (e.g. task design and the use of protocols), (3) staff factors (e.g. knowledge and skills), (4) team factors (e.g. supervision and communication), (5) work environmental factors (e.g. staffing levels and environment), (6) organisational and managerial factors (e.g. policy and financial resources), and (7) institutional context factors (e.g. economic and regulatory context).

The next section explains how these multiple factors contribute to accidents through the use of different accident models.

2.4.2 UNDERSTANDING ACCIDENTS

An accident is defined as an *“undesired event giving rise to death, ill health, injury”* (BSI 2004a). Similarly, in healthcare, an accident is defined as *“an incident that happens unexpectedly and unintentionally, and which may result in damage or injury”* (House of Commons 2015), and it can be interchangeably used with the terms: incident, adverse event, critical incident and sentinel event (Aronson 2009; Woodward et al. 2004). However, an incident or an adverse event can result in all degrees of harm or loss (e.g. no harm or loss and significant harm or loss), whereas a critical incident or a sentinel event results in harm or loss with severe consequences (e.g. severe harm or death).

Since system elements are subject to failures in complex systems, there is always a possibility of an accident occurring (Harris 2006). However, accidents resulting in severe consequences do not often occur and, therefore, learning from them is difficult (Venkatasubramanian and Zhang 2016). To address this challenge, accident models have been developed, and accident causation analysis has been

conducted to understand the nature of accidents and their contributing factors (Li et al. 2017; Luo et al. 2013).

A number of models have been developed to understand accidents. Hollnagel (2004) divides these models into three categories, sequential, epidemiological, and systemic, as shown in Figure 2.5. Both sequential and epidemiological models represent cause and effect thinking, which considers accidents as predictable and resultant phenomena. Systemic models, on the other hand, define accidents as emergent phenomena, in which accidents are considered normal or natural and where something happens unpredictably due to the complex conditions (Hollnagel 2004).

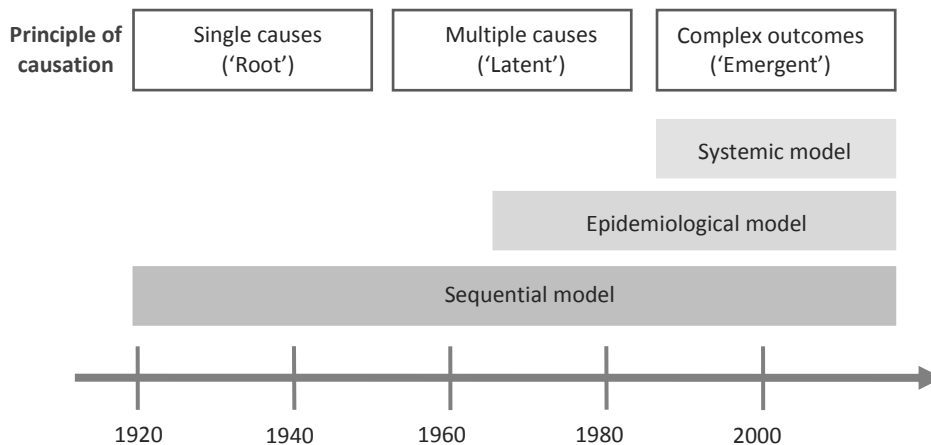


Figure 2.5 Summary of a history of accident modelling adapted from SIA (2012)

2.4.2.1 Sequential accident models

Sequential models imply that accidents transpire as a result of sequential events occurring in a specific order (Hollnagel 2004). A specific type of accident potentially follows the same route and series of events (Huang et al. 2004). Figure 2.6 demonstrates a sequential accident model in a normally functioning system. An unexpected event initiates a sequence of events and leads to an unexpected consequence.

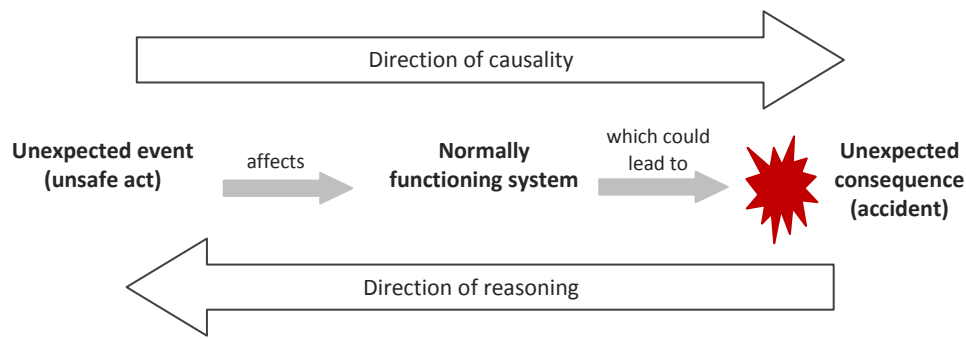


Figure 2.6 Sequential accident model adapted from Hollnagel (2004)

The first model for this way of thinking was developed by Herbert Heinrich in 1931, and is called the Domino Model, Domino Theory, or Domino Effect (Heinrich 1931). Based on this model, an accident is considered to be a link in the chain, and it results from one of five factors falling in a sequence. These factors are: (1) the social environment, (2) the fault of the person, (3) unsafe acts (mechanical and physical hazards), (4) the accident and (5) injury (Heinrich 1931). In other words, all accidents result from the social environment leading to a fault of person, which results in unsafe acts, which lead to an accident and, in turn, an injury. Figure 2.7 demonstrates the domino model.

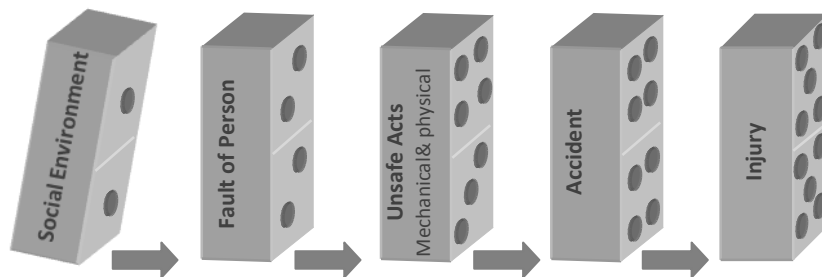


Figure 2.7 Domino model of accident causation adapted from Heinrich (1931)

The domino model suggests that accidents can be prevented through removing one of these five blocks, so that the domino effect is interrupted (Hollnagel 2004). Among these five blocks, Heinrich focused on the removal of the fault of person. His study found that 88 percent of preventable accidents result from the unsafe acts of persons, 10 percent result from the unsafe machines and 2 percent are unavoidable (Heinrich 1931). Thus, this model considers humans as the main reason for accident.

Risk management techniques and methods have been developed based on the logic of the sequential models such as Event Tree Analysis (ETA) (Watson 1961) and Five Whys (Ohno 1988). However, these techniques may identify different causes. Card (2016), for instance, demonstrates this by explaining a wrong medication incident through the use of the Five Whys technique. The incident could be explained by a wristband not being checked due to the wristband being missing. This could also be explained by the wristband printer being broken because of a label jam, due to poor product design (Battles et al. 2006). However, the cause of the missing wristband could also be thought of as stemming from a broken printer which could in turn be explained by the purchasing process of the printer being poor, which again in turn stems from the fact that non-clinical equipment is not seen as safety-critical in the organisation (Card 2017). This indicates that different individuals may identify a different root cause(s) by the use of Five Whys, which makes the technique less reliable.

Although the sequential models are attractive as they lead people to think in the style of a domino effect (Dorner 1980), they have been claimed to over-simplify the cause and effect relations regarding the accidents in complex systems (Hollnagel 2004). As a consequence, epidemiological models were developed for a better understanding of accidents (Hollnagel 2004).

2.4.2.2 Epidemiological accident models

Epidemiological models view accidents as a result of a combination of factors, which include environmental conditions, performance deviations leading to unsafe acts as well as latent conditions (Figure 2.8). Such factors pass through system barriers and defences, and, in turn, can lead to accidents. Adding barriers, therefore, can prevent accidents in these models (Hollnagel 2004). However, it should be mentioned that adding new barriers might raise new risks in the system.

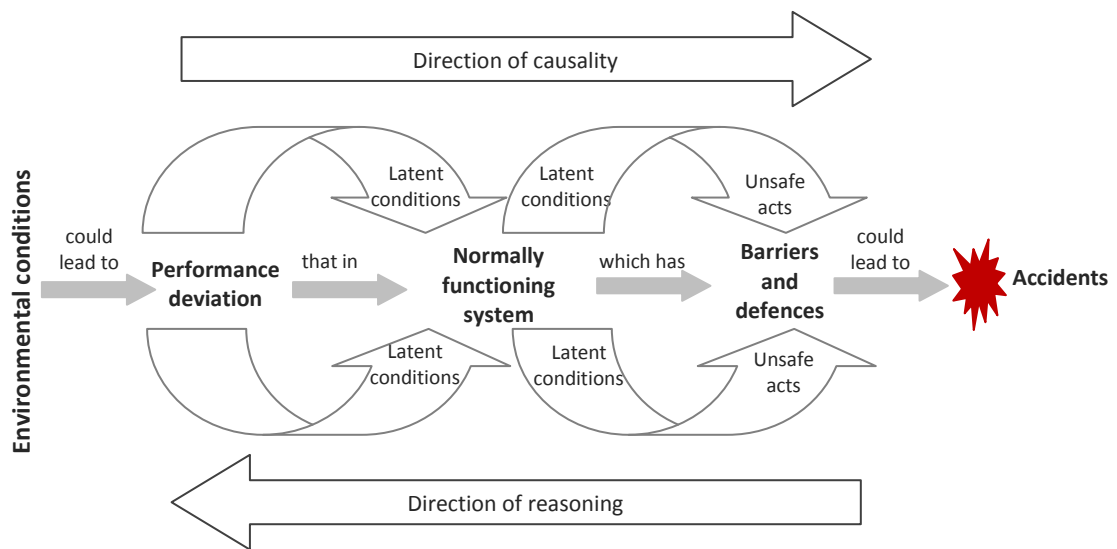


Figure 2.8 Epidemiological accident model adapted from Hollnagel (2004)

The *Swiss Cheese Model* is a well known epidemiological model (Reason 1997). It has been widely accepted in healthcare (Perneger 2005). This model emerges from a triggering event through different levels of barriers from institution to technical. Since these barriers might not be perfect, weaknesses may exist due to latent conditions and active failures. If hazards break through all the “holes”, this could lead to harm or loss (Vincent 2010). Figure 2.9 illustrates the Swiss cheese model applied in a hospital setting.

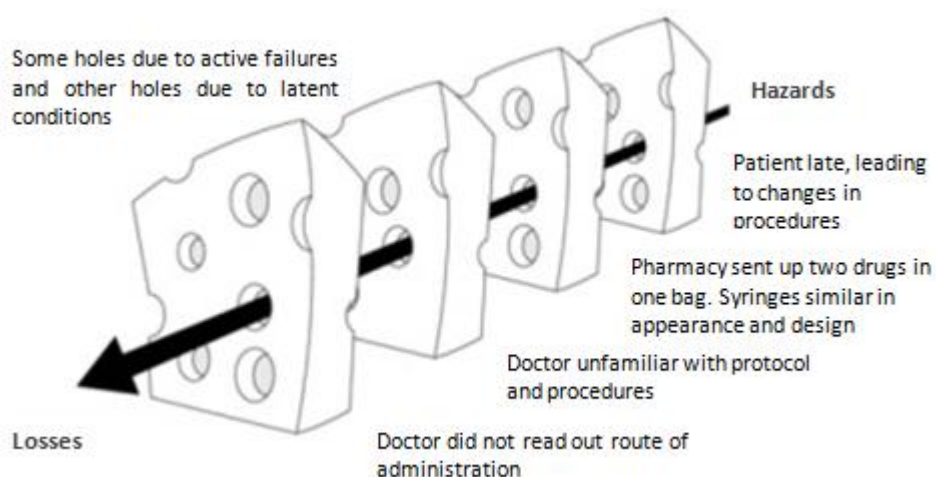


Figure 2.9 Reason's Swiss cheese model adapted from Vincent (2010)

Epidemiological models provide a notion of latent conditions and a basis for understanding accidents in complex systems (Hollnagel 2004). However, epidemiological models still follow the principles of sequential models, and their focus remains on system components rather than on the overall system (Hollnagel et al. 2006). Additionally, epidemiological models tend to predict the general likelihood of an event without explaining where and when it may happen. Thus, they show the general *health* of the system and, in turn, predict the general failure types (Reason et al. 2006). It has also been argued that such models are unresponsive to the major changes in recent decades in the types of hazards, the nature of accidents, the complexity of industries, technology, regulations and public views of safety (Hollnagel 2004; Leveson 2004).

Accidents may occur as a result of unsafe interaction of system components even if all components operate successfully (Leveson 2004; Leveson 2017; Sujan et al. 2017). Hence, systemic accident models were developed to address the challenges of epidemiological models (Hollnagel 2004).

2.4.2.3 Systemic accident models

Systemic accident models have been built on systems theory. In systems theory, multiple factors act concurrently and accidents arise from combined mutually interacting factors (Klockner and Toft 2015; Leveson et al. 2016). Therefore, the interaction of these factors must be considered to understand the accidents and prevent similar ones (Hollnagel 2004; Sheridan 1992; SIA 2012). Figure 2.10 illustrates all the events which contribute to an accident.

Since each event could be preceded by other events, there is no direction of causality in this model. Events are linked to each other, and they are explained by considering their blunt and sharp-ends. While people interact with the hazardous process at the sharp-end, factors at the blunt-end also contribute to accidents. These factors include government, regulatory, company, management and local workplace factors as well as social norms (Hollnagel et al. 2013; Woods et al. 1994).

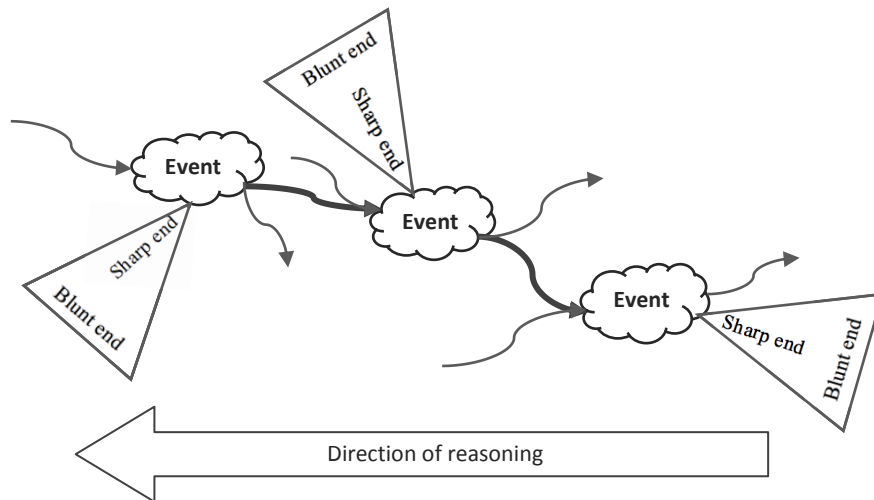


Figure 2.10 Systemic accident model adapted from Hollnagel (2004)

The key concepts of systemic models, are provided by Rasmussen (Rasmussen 1997). His risk management framework provides a six-level socio-technical system (Figure 2.11). These levels are government, regulators and associations, company, management, staff and work. His model also considers a range of research disciplines (e.g. political, economics and psychology) and environmental stressors (e.g. change in political climate, technology and financial pressure) by demonstrating the integration between all factors (Dallat et al. 2017; Rasmussen 1997). This model indicates that risk management is part of a larger system, and any change in one part of the system has an influence on the risk management system.

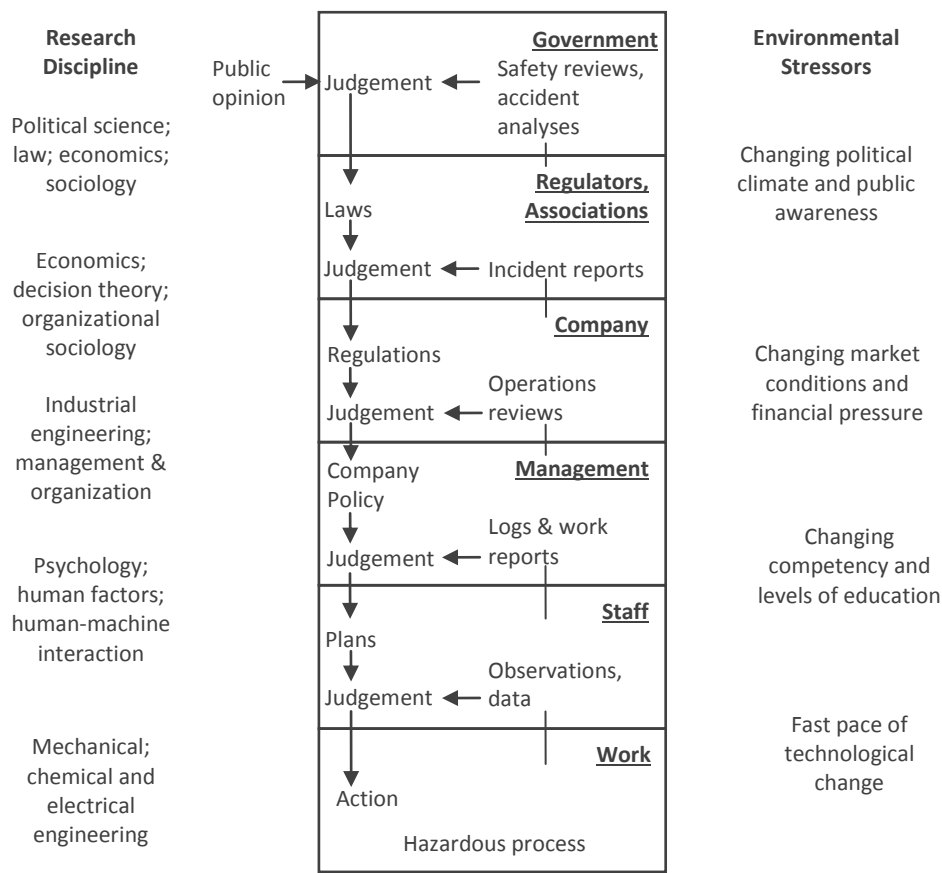


Figure 2.11 The Socio-technical system involved in risk management Rasmussen (1997)

Having built on this risk management framework, Rasmussen introduced the Accimap approach to analyse accidents (Rasmussen 1997). His works have inspired a number of researchers (Le Coze 2014; Le Coze 2017).

The Functional Resonance Accident Model (FRAM) was one of the first models to recognise the system approach in accident modelling. FRAM describes everyday activities as functions (Hollnagel et al. 2014). Functions are represented by hexagons, and six different characteristics are defined for each function. These characteristics are input (I), output (O), preconditions (P), resources (R), time (T) and control (C). Functions are then linked to each other to represent the relations and dependencies (Hollnagel 2012). Figure 2.12 presents part of the FRAM network for a drug dispensing procedure and illustrates multiple functions (activities) that have been identified as relevant to this procedure, and the interactions among them.

sequential models. For instance, FTA and ETA are still successfully used in nuclear industries. Accident models can, therefore, be selected depending on the system needs, safety objectives and the complexity of the situations and the different parts of the healthcare system may thus require the use of different or a combination of accident models. All accident models were developed to understand how accidents occur, and risk assessment processes were developed to help prevent them. Yet, it should be noted that accident models provide a basis for risk assessment practice (Hollnagel 2004).

Risk assessment is a way of preventing unwanted events or at least minimising their negative consequences (Hollnagel 2014a; Hollnagel 2008). However, the majority of the risk assessment techniques are built on the sequential and epidemiological accident models and thus they can only reveal sharp-end failures (Dallat et al. 2017). However, this could be also due to the way in which these techniques are applied. While these techniques still add value to risk assessment practices, this research considers that risks should be assessed by determining several factors with a systems approach to minimise harm before it occurs. These factors include sharp-end, blunt-end, human performance variability and missing barriers through a consideration of all system elements and the interactions between them.

The following section explains the science behind risk assessment in the context of safety risk management.

2.5 RISK ASSESSMENT

Risk assessment is a fundamental part of risk management (BSI 2009; NIST 2012). It is an overall process of risk identification, analysis and evaluation (ISO 2009). Figure 2.13 illustrates the risk assessment process as part of the risk management process provided by British Standards (BSI 2009).

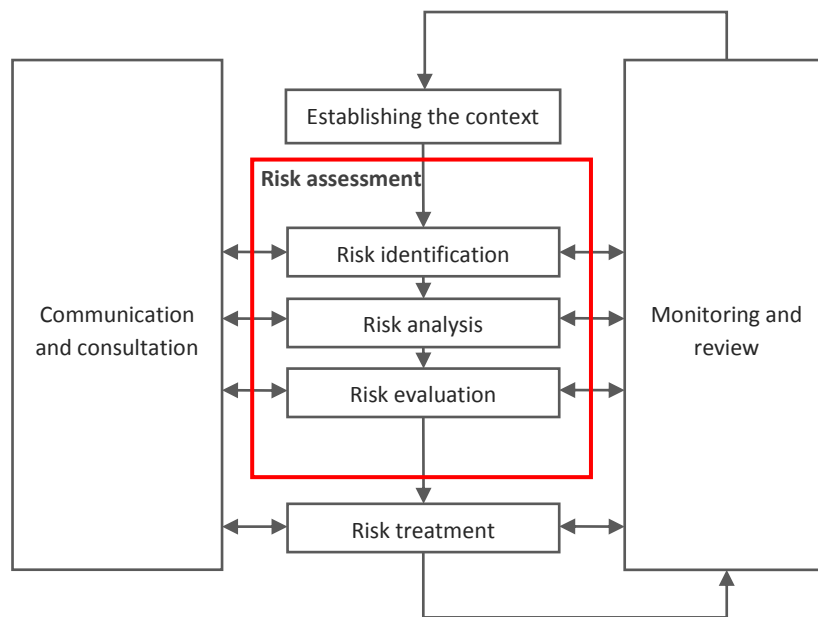


Figure 2.13 Risk assessment process BSI (2009)

Risk assessment provides evidence-based information to make risk-based decisions and to satisfy organisational objectives (BSI 2010; Torabi et al. 2016). To do so, risk assessment addresses the following questions: “*What can happen and why?*”, “*What are the potential consequences?*”, “*What is the probability of its occurrence?*”, and “*Are there any factors that mitigate the consequence or probability of the risk?*” (BSI 2010; Kaplan and Garrick 1981).

Since the risk assessment process is part of the risk management process, the next section provides an overview of risk management.

2.5.1 AN OVERVIEW OF RISK MANAGEMENT

Risk management is defined as “*coordinated activities to direct and control an organisation with regard to risk*” (ISO 2009). Risk management is part of governance and organisational management (ISO 2017).

In healthcare, risk management is defined as “*the process of identifying, assessing, analysing and managing all potential risks*” (NPSA 2006). Risk management has been an essential component of the healthcare system since the 1970s (Kuhn and Youngberg 2002). It traditionally focused on the reduction of

litigation costs, and then moved on to the reduction of the frequency of adverse events (Vincent 1995; Vincent and Amalberti 2016). Since then, risk management in hospitals has become a part of clinical governance to improve the quality and safety of patient care (Cagliano et al. 2011; NPSA 2006).

In hospital settings, incident investigation and risk assessment are two essential risk management applications to ensure safety. Risk management can thus be implemented before, during and after adverse events (Proag and Proag 2014). However, most applications to manage risks are positioned after the occurrence of an adverse event (Sujan et al. 2016). Healthcare organisations have, therefore, mostly focused on incident investigation by asking “*What went wrong?*” rather than on risk assessment by asking “*What could go wrong?*”.

However, risk management cannot solely rely on responding to incidents. Hazards and controls change over time in dynamic environments. Consequently, incidents may not occur in the same way as they have occurred before (Rasmussen 1997). Instead, risk assessment, which is the focus of this research, could help understand potential risks, determine ways to reduce them and monitor the change. A need for such a proactive approach has also been highlighted by healthcare researchers to manage risks before they lead to adverse events (Cagliano et al. 2011; Hudson 2003; Hudson et al. 2012; Sujan et al. 2017).

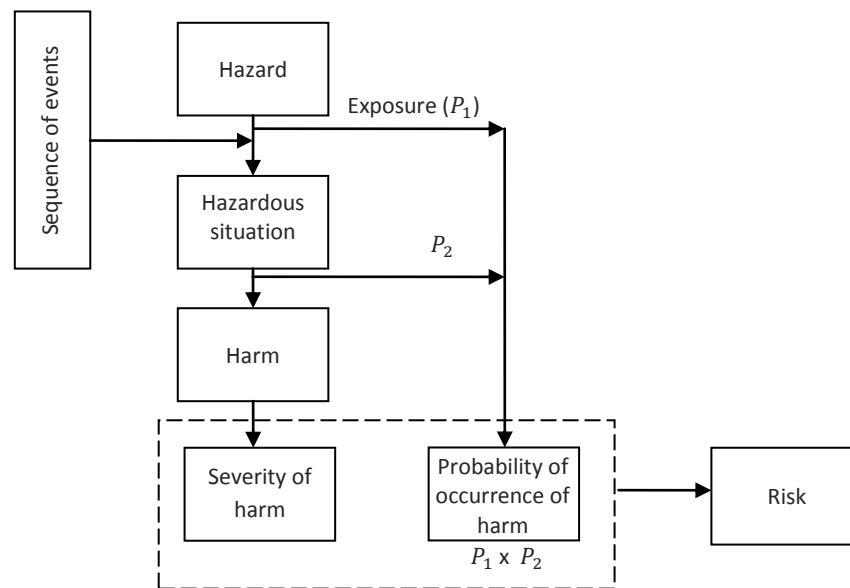
Before moving on to explain risk assessment in detail, the terms *hazard* and *risk* are described to understand risk assessment better.

2.5.2 DEFINITIONS OF HAZARDS AND RISKS

2.5.2.1 Hazards

A hazard is something that may cause harm or loss as a result of the physical properties, materials, operating conditions and designs involved (Crowl 2003; Stephenson 1991). Similarly, in the healthcare context, hazards are defined as

“situations with the potential to cause harm” (NPSA 2007). For instance, shallow water constitutes a hazard and diving itself is an action that precipitates the risk (Beer and Ziolkowski 1995); a medicine itself constitutes hazard, and taking an overdose that precipitates the likelihood resulting in severe harm is a risk (NPSA 2007). The relationship between risk and hazard is illustrated below in Figure 2.14.



NOTE P_1 is the probability of a hazardous situation occurring.
 P_2 is the probability of a hazardous situation leading to harm.

Figure 2.14 Pictorial representation of the relationship of hazard, sequence of events, hazardous situation and harm BSI (2012)

As shown in Figure 2.14 the exposure to a hazard in a sequence of events leads to a hazardous situation, which may lead to harm. Risk is the consideration of the probability of the occurrence of harm and its potential severity.

2.5.2.2 Risks

There has been some ambiguity in the understanding of risk terms stemming from conflicting values and human judgement and knowledge (Aven 2012a; Aven 2010; Johansen and Rausand 2015). In fact, there are a range of definitions provided for the term risk. The majority of these definitions refer to something

negative, some to uncertainty and some to an impact on objectives (Aven 2012a; Aven 2012b; Suddle 2009). For instance, risk is considered as an event, a consequence, an uncertainty and a combination of likelihood and consequence. The key definitions regarding these aspects are given below. A risk is defined as:

- *“the likelihood of an event, hazard, threat, or situation occurring and its undesirable consequences; a potential problem”* (BSI 2004b).
- *“effect of uncertainty on objectives”* (BSI 2009).
- *“the chance of something happening that will have an impact upon objectives”* (AS/NZS 1999).
- *“the combination of likelihood and consequence of a hazard being realised”* (NPSA 2007).
- *“expected loss” or “an event or consequence”* (Aven 2012b).

Actually, there is not a single perfect definition that can fit all circumstances. For instance, risk in finance might refer to both potential positive and negative impacts with a consideration of uncertainty, whereas risk in the safety context often refers to something negative. So, the best definition for one particular organisation or industry might not be the best for another. The solution is to select the most appropriate definition and to ensure that everyone in the organisation treats risks by considering the same definition.

Regarding all given definitions, a risk could be something that threatens the financial or operational objectives. Indeed, a variety of classification schemes have been provided in the literature to categorise risks. For instance, the ISO risk management standards categorise risks as strategic risks, programme risks, project risks, financial risks, safety risks, compliance risks and operational risks (BSI 2011b). Furthermore, the Orange Book categorises risks by determining external environment (e.g. political and legal), existing operations (e.g. delivery and capacity) and change (e.g. policy, projects and targets) (HM Treasury 2004).

Having provided basic terms, risk assessment process in hospitals is explained in the next section.

2.5.3 RISK ASSESSMENT IN HOSPITALS

Risk assessment is a process to analyse the risks to the whole system, including patients, staff, visitors and organisations (Kavaler and Spiegel 2003; NPSA 2006; Francis 2013). To do so, risk assessment in the context of safety seeks to answer the questions: “What can go wrong?”, “How bad is it?”, “How often does it occur?”, and “Is there a need for action?” as in Figure 2.15 (NPSA 2006).

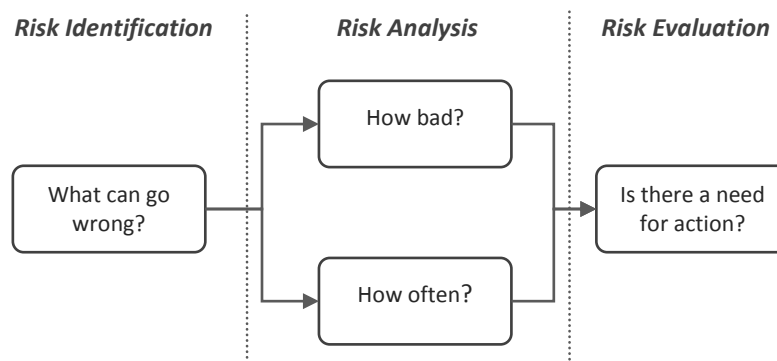


Figure 2.15 Key four questions to assess risks NPSA (2006)

A number of risk assessment methods are used to address these questions. In some cases, healthcare staff respond to such questions by using their professional judgement, without using prospective hazard analysis techniques; in other cases organisational risk assessment forms or other tools and techniques may be used. These include brainstorming (Carroll 2009; Holloway and Wheeler 2010; NPSA 2006), safety walkabouts (Singer and Tucker 2014; Rotteau et al. 2014), risk matrices (Solberg et al. 2015; Ward et al. 2010) and checklists (e.g. surgical safety checklists, health and safety checklists and checklists for medical devices) (Devcich et al. 2015; Gawande 2010; Ong et al. 2015).

In NHS hospitals, the documentation of all risks is recommended and a risk register template is provided. A risk register system is widely used to record identified risks and help diagnose problems in the organisation (GGI 2009; Illingworth 2015a). The risk register system includes the risk reference data, the risk owner, a risk description, the likelihood and impact ratings of the risk, the risk proximity (when the risk is likely to occur), action plans, action owners, and a completion date for each suggested action (NHS England 2015c).

In addition, the application of risk assessment is supported by and has been investigated by some external organisations. These organisations include NHS Improvement, which gathers the National Patient Safety Agency (NPSA) and the National Reporting and Learning System (NRLS) under its umbrella, the National Health Service Litigation Authority (NHSLA), the Care Quality Commission (CQC), and the Health Foundation. A number of key reports have been published by these organisations such as *Continuous Improvement of Patient Safety* (Illingworth 2015a), *Seven Steps to Patient Safety* (Woodward et al. 2004), *Risk Assessment Programme* (NPSA 2006), and *Healthcare Risk Assessment Made Easy* (NPSA 2007).

Continuous Improvement of Patient Safety argues the need for change in the way safety is understood and improved. The report highlights the necessity of assessing risks proactively before harm occurs (Illingworth 2015a).

Seven Steps to Patient Safety explains the importance of risk assessment, and its integration into everyday activities. Risk assessment is explained as a process to help organisations recognise a wide range of risks that they face, to understand their ability to control these risks, and to determine the likelihood and consequences of these risks (Woodward et al. 2004).

Risk Assessment Programme provides more details on the application of risk assessment. The risk assessment process is divided into four tasks: planning the assessment (e.g. defining key objectives, scope and resources), mapping out the service to be assessed (e.g. defining components and activities), meeting to conduct the assessment, and reviewing the assessment outcomes. The report states that risk assessment should involve those staff connected to the assessed risk. It also provides some information on the currently used risk assessment methods in healthcare (NPSA 2006).

Healthcare Risk Assessment Made Easy provides a summary for a simplified risk assessment process (NPSA 2007).

However, there has been little evidence to explain the general principles behind risk assessment in healthcare, and to propose a comprehensive risk assessment approach. Yet, a number of challenges have already been identified in the healthcare literature regarding the current risk assessment practices. Eidesen *et al.* (2009) argue that these challenges are mainly in relation to the fundamentals of risk assessment and its use. Specifically, these challenges are about how to express risk, how to analyse it, how to determine organisational factors within risk assessment as well as how to use risk assessment as a tool to ensure patient safety (Eidesen *et al.* 2009).

Berwick *et al.* (2013) argue that responsibilities for safety and quality concerns are diffused. Consequently, responsibilities might not be clearly owned: for some tasks there might be multiple people in charge whereas for some others no-one is in charge. Furthermore, Illingworth (2015a) reports that risk register systems have been used as a bureaucratic data collection system. This might result in lack of understanding of the risks as well as registering risks without aiming to managing them. Vincent *et al.* (2013) state that risk registers have been used as a tick-box exercise to meet regulatory requirements. Consequently, risk assessment can be insufficiently conducted and may focus mainly on regulatory requirements instead of risk reduction.

Additionally, it is claimed that prospective hazard analysis techniques are not used much to assess risks, and if used, they may be used without training (Card *et al.* 2013; Card *et al.* 2012b; Vincent *et al.* 2013; Ward *et al.* 2010). This could potentially lead to inadequate assessments, and, in turn, ineffective measures could be taken to manage the assessed risks.

What is more, risk scoring can be subjective (Card *et al.* 2013). Most of the risks are estimated based on an individual's knowledge. Therefore, different individuals may prioritise the same risk differently due to their varied risk perception, which is a reflection of social (e.g. culture and values) and human (e.g. individual profession, belief and values) dimensions (Wood *et al.* 2012). Consequently, individuals may under- or over-value some of their risks resulting in organisations treating their risks according to biased estimations.

Given all these challenges, there is great potential to improve current risk assessment practice in hospitals. In contrast to healthcare, safety-critical industries (i.e. aviation, nuclear, and chemical industries) are more advanced regarding their risk assessment applications (Audit Commission 2009; Rogers 2002; Sujan et al. 2015). For instance, biased estimations are minimised by the involvement of multidisciplinary skilled teams, by the use of a variety of risk assessment techniques, and by the use of quantitative data as well as qualitative data (BSI 2010). In addition, a large number of extensive guidelines have been established which provide a context to risk assessment, including how to express risk, how to analyse it, which techniques to use and how to conduct risk assessment. For instance, the US Department of Defence (DoD) has established a military standard for safety (DoD 2008), the Federal Aviation Administration (FAA) has introduced a safety management system manual (FAA 2004), the Committee of Sponsoring Organizations of the Treadway Commission (COSO) has provided enterprise risk management guidance (COSO 2004), and the National Aeronautics and Space Administration (NASA) has provided a risk management handbook (NASA 2011). Furthermore, the International Organisation for Standardisation (ISO) has published a variety of guidance material on risk assessment for the use of all industries as well as for the use of specific industries (e.g. EN ISO 17666, ISO 31000, and ISO 31010).

As there are a large number of risk assessment guidelines for safety-critical industries, this research aims to improve the current risk assessment practice in hospitals by learning from them. Indeed, the healthcare industry has been encouraged to learn from safety-critical industries to improve safety (Department of Health 2000; Kohn et al. 2000), and safety-critical industries have more mature safety management practices than hospitals (Sujan et al. 2016). However, the applications in safety-critical industries may need to be tailored before being transferred to healthcare. Table 2.1 demonstrates comparisons between healthcare and safety-critical industries relevant to tailoring risk assessment practice based on research which has identified the characteristics of these industries.

Table 2.1 Comparisons between healthcare and safety-critical industries

Healthcare industry	Safety-critical industries
Dynamic and complex (Cook and Rasmussen 2005; Dekker and Leveson 2015)	Dynamic and complex (Vincent 2006)
Service delivery (Kapur et al. 2015)	Mostly product manufacturing and service delivery in aviation (Kapur et al. 2015)
Vulnerable individuals are the inputs of the care process (Kapur et al. 2015; NPSA 2010)	Raw materials are often the inputs of process (Kapur et al. 2015)
A diverse set of activities and more manual process (Vincent 2010)	Less diversity in activities and more automated processes (Vincent 2010)
Some parts loosely coupled (easier to understand system behaviour) and some others tightly coupled (Cook and Rasmussen 2005)	Mostly tightly coupled (hard to estimate system behaviour) (Cook and Rasmussen 2005)
Lack of safety training (Pronovost et al. 2009)	Skilled and highly trained staff (Pronovost et al. 2009)
Lack of safety standards and regulations (Dixon-Woods and Pronovost 2016; Macrae and Vincent 2014)	Adequate standards and regulations to support and control safety (Rogers and Gaba 2011; Vincent 2010)
Individuals at risk (Rogers and Gaba 2011)	Many lives at risk (e.g. aviation) (Rogers and Gaba 2011)
Thousands of incidents are reported annually, but there is still underreporting (Benn et al. 2009; Noble and Pronovost 2010)	Hundreds of incidents are reported annually with better reporting culture (Benn et al. 2009; Buckle et al. 2003)
Lack of feedback from the reported incidents (Benn et al. 2009)	Better lessons learnt and feedback (Benn et al. 2009)
Difficult to delay processes if there is a safety concern (productivity is prioritised over safety) (Hollnagel et al. 2015)	Process is stopped if there is a threat (safety is over productivity) (Hollnagel et al. 2015)
'Speaking Up' is used to raise safety concerns (Francis 2015)	'Just culture' is used to encourage staff raise safety concerns (Francis 2015)
Less value is given to safety activities and activity is predominantly reactive (Sujan et al. 2015)	More value is given to safety activities, and reactive and proactive activities are balanced (Sujan et al. 2015)
Not designed to be safe (Illingworth 2015a)	Designed to be safe (Illingworth 2015a)
Safety is not a part of everyday action (Illingworth 2015a)	Safety is a part of everyday action (Illingworth 2015a)
Risk register system is used as a bureaucratic data collection exercise (Illingworth 2015a)	Risk register is used to diagnose problems (Illingworth 2015a)
Lack of risk assessment techniques used (Ward et al. 2010)	A large number of techniques have been developed and used (Ward et al. 2010)

The next section provides detailed information on good risk assessment practice to provide a better understanding of what this is.

2.6 GOOD RISK ASSESSMENT PRACTICE

Thirty-five national and international risk assessment standards (see Appendix 1 for a list of these standards), which have been established by well-respected standardisation bodies, regulatory bodies and professional organisations, are here reviewed to explain risk assessment practice. Within this thesis, such standards are used to describe prescribed good risk assessment practice since those standards have been judged by well respected institutions such as the British Standards Institution (BSI) and the International Organisations for Standardisation (ISO) and recognised by a large number of organisations and researchers in a range of industries. More importantly, such standards are developed and reviewed by multiple technical committees that comprise the representatives of standard users, local and central government, industry bodies and research and testing organisations.

As risk assessment is not a stand-alone activity: good risk assessment practice should determine activities prior, during and after risk assessment.

2.6.1 PRIOR TO THE RISK ASSESSMENT

Prior to the risk assessment practice, the assessment context should be established by determining the following: internal parameters (e.g. culture, policies and perception of internal stakeholders), external parameters (e.g. social environment, key trends and perceptions of external stakeholders), responsibilities, assessment methodology, and risk criteria (BSI 2010). Organisational risk assessment policies or procedures provide many of these details.

Risk assessment methods should be also selected prior to undertaking the risk assessment. There are a range of methods that can be used; however, the most appropriate methods should be selected. BS EN ISO 17776 divides potential methods to support risk assessment into four categories: (1) experience/judgement, (2) checklists, (3) codes/standards, and (4) structured review techniques. Using experience is appropriate when there is adequate knowledge and expertise. Checklists are useful when all hazards are known and identified. Codes and standards refer to a list of statements for recommended practice. Structured techniques are developed to assess unforeseen hazards and unintended events which may be inadequately assessed by other methods (BSI 2002). However, no single technique is perfect by itself (Redmill et al. 1999). The most suitable risk assessment techniques can be selected based on objectives, the needs of decision makers, an assessor's competence with the tool, the nature of risk, the level of uncertainty, resource availability (e.g. skills and budget), information availability, or regulatory requirements (BSI 2010; BSI 2011b; Crowl 2003; Mullai 2006).

In addition, the system to be assessed should be described prior to the risk assessment. A clear understanding of the system leads to the recognition of all potential risks and, in turn, leads to a more effective risk analysis (Redmill et al. 1999; DoD 2008). The system description includes the identification of system objectives, system boundaries, system parts and the interactions of these parts (FAA 2004; CAA 2010; ORR 2015; RSSB 2014). System modelling diagrams can be used to describe systems. Table 2.2 provides six such diagrams, indicating the suitability of each diagram type (task, information, organisational, system, flow and communication) to system attributes in healthcare.

In Table 2.2, larger ticks indicate a significant suitability to capture those system attributes, whereas small ticks indicate partial suitability and no ticks indicate that there is no suitability for the provided diagram type.

Table 2.2 Suitability of different diagram types for representing a range of system attributes in healthcare Ward et al. (2010)

Characteristics of Interest	System Mapping Approaches					
	Task	Information	Organisational	System	Flow	Communication
Process and procedure (e.g. patient pathways)	✓	✓		✓	✓	
Human behaviour (e.g. performance measures)	✓			✓	✓	
Role and responsibilities (e.g. team working)			✓		✓	
Communication (e.g. referral)		✓		✓		✓
Human-technology interface (e.g. medication devices)	✓			✓		✓
Procurement and supply (e.g. medication flow)			✓	✓	✓	✓
✓ significant match ✓ partial match						

Each diagram type is briefly described below:

Task diagrams represent the hierarchical structure of operations or tasks and plans (Ward et al. 2010).

Information diagrams demonstrate the hierarchical structure of documents or information to understand issues regarding documentation such as the level of usage of electronic documents and the degree of standardisation of documents (Jun et al. 2009).

Organisational diagrams show the hierarchical structure of the people or roles within the organisation(s) (Ward et al. 2010).

System diagrams describe the transformation of data or objectives to activities, including where to store data and how to sequence activities (Ward et al. 2010).

Flow diagrams depict the sequences of process steps visually for a better understanding of the process (Jun et al. 2009).

Communication diagrams represent information and material interactions between stakeholders to understand the relationships among different hospitals, departments, teams and individuals (Jun et al. 2009).

Jun *et al.* (2009, 2010) claim that the use of flow charts and system diagrams can allow for an effective description of system attributes (see Table 2.2). Indeed, in healthcare, flowcharts have been predominantly used to describe systems (DeRosier et al. 2002; Jun et al. 2010).

2.6.2 RISK ASSESSMENT PROCESS

The risk assessment process consists of three steps: risk identification, risk analysis and risk evaluation (Figure 2.13).

2.6.2.1 Risk identification process

The risk identification process involves finding, recognising and describing risks (BSI 2009) alongside the consideration of risk sources, events, their causes and their consequences (BSI 2010; Haimes 2009; BSI 2014).

Hazards can be determined as risk sources (ISO 2009). Additionally, contributory factors can also be determined to be risk sources. For instance, the COSO Enterprise Risk Management Framework lists nine factors that could potentially give rise to an event (COSO 2004). These are economic, natural environment, political, social, technological, infrastructure, personnel, process and technology. Similarly, Vincent *et al.* (1998) identify seven factors that influence the safety and quality of clinical practice. These factors are patient characteristics (e.g. personality and condition), task (e.g. task design and the use of protocols), staff (e.g. knowledge and skills), team (e.g. supervision and communication), work environment (e.g. staffing levels and environment), organisational and management (e.g. policy and financial resources), and institutional context (e.g. economic and regulatory context). In addition, Simsekler *et al.* (2014) propose a risk source categorisation scheme (with patient-sourced, staff-sourced, task-

related, communication, equipment-related, environmental and organisational categories) to identify risks in healthcare after comparing multiple risk source categorisation schemes.

An event is described to be *“occurrence or change of a particular set of circumstances”* (ISO 2009). Events should be identified by considering multiple operation modes, including normal, degraded and emergency modes (ORR 2015), and should be linked to objectives (COSO 2004; BSI 2009). Additionally, events should be categorised in order to help management determine risks better. A categorisation scheme is provided by COSO and includes economic, population health, service delivery, human resources, technology and natural environment event categories (COSO 2004). However, this classification can be tailored depending on the nature of the events and organisational strategies.

As indicated by accident models, several factors lead to accidents. There might be several causes for a single event (BSI 2011b). While causes could be straightforward in some cases, causation may not be evident for other cases (BSI 2009). Thus, risk sources need to be determined to define the factors that contribute to the occurrence of the potential events.

Events have potential consequences, which may have impact people, organisations and the environment with both immediate and knock-on effects (ISO 2000; BSI 2009; BSI 2010).

2.6.2.2 Risk analysis process

A risk analysis process determines the nature and the level of risk (BSI 2009). In so doing, risk analysis involves the analysis of consequence, likelihood and uncertainty as well as the consideration of existing controls to prevent or mitigate risks (NASA 2011; BSI 2010; BSI 2009).

Consequence analysis determines the severity of both immediate and knock-on consequences relating to objectives (BSI 2010). Since a single risk could lead to a number of different consequences in the same consequence domain (BSI 2011b),

the severity of the consequence can be determined by considering *the worst credible* consequence (AFSC 2000; CAA 2010; FAA 2004; NASA 1999). This can be defined as the most unfavourable condition, but reasonable, condition (FAA 2004). However, this might add more complexity to the risk assessment practice. However, organisations can identify their own strategies by ensuring that everyone uses the same strategy.

Likelihood is explained to be a chance of something happening, which can be estimated by using probability or frequency (ISO 2009). Historical data, predictive techniques (e.g. scenario analysis and decision trees) and expert opinion can be used. Historical data can be used to determine the probability of the reoccurrence of an event. Predictive techniques can be used when historical data are inadequate or unavailable to estimate probability of an event. Expert judgement can be used when all relevant information is available (BSI 2010).

Uncertainty is defined as *“the state, even partial, of deficiency of information related to, understanding or knowledge of an event, its consequences, or likelihood”* (ISO 2009). Uncertainty might result from limited data or poor data quality as well as from sociological, psychological and cultural factors (ISO 2013; NASA 2011). To estimate the degree of uncertainty, the availability and quality of information regarding the risk should be known by assessors (BSI 2010).

NASA lists five generic factors for ranking uncertainty, which are (1) the uniqueness of the risk (*“Is this risk issue unique?”*), (2) the cross-cutting character of the identified risk event (*“Does this risk affect a large number of functions?”*), (3) the complexity of the risk issue (*“Does the risk involve complex interactions?”*), (4) the propagation potential of the event resulting in more severe consequences (*“Could this risk lead to a propagation of events?”*), and (5) the detectability of the risk (*“Is there anything that inhibits the ability to detect the full extent of risk?”*) (NASA 2011). Among these factors, detectability is also used with Failure Modes and Effects Analysis (FMEA) to estimate the criticality of a risk.

Additionally, risk analysis determines existing controls and their effectiveness (BSI 1996; BSI 2009). Controls are measures to prevent or mitigate risks as well as

recover from the occurrence of these risks (ISO 2015; BSI 2011b). Controls compromise safeguards and barriers. Safeguards aim to mitigate human error through local warnings and signs, alarms and human machine-interface (McLeon et al. 2010). Barriers can be in relation to design features, hardware, process and tasks, or a combination of these (ISO 2015).

Card *et al.* (2014) describe three hierarchies of risk controls, which are elimination (developing controls to eliminate the source of harm), design controls (developing engineering controls with a less reliance on human beings), and administrative controls (developing controls by relying on human beings) (Card et al. 2014a; Card et al. 2014b). Effectiveness of existing controls is assessed by considering three questions: *“What are the existing controls for a particular risk?”*, *“Are those controls capable of adequately treating the risk so that it is controlled to a level that is tolerable?”*, and *“In practice, are the controls operating in the manner intended and can they be demonstrated to be effective when required?”* (BSI 2010).

Following that, the level of risk is measured by combining likelihood and consequence after assessing of the effectiveness of existing controls (BSI 2009). Detectability can be also considered in addition to likelihood and consequence to measure risk criticality level (BSI 2010).

2.6.2.3 Risk evaluation process

The risk evaluation process assists in making decisions in relation to risk tolerability and prioritisation (BSI 2014; BSI 2009). To determine the tolerability of a risk, the estimated risk level is compared with the risk criteria (BSI 2009).

Risk criteria are *“terms of reference against which the significance of a risk is evaluated”* (ISO 2009). So, risk criteria are the reference points used in making risk-based decisions. Therefore, it is essential to set risk criteria well when establishing the assessment context. Risk criteria can involve the consideration of organisational priorities, the needs of stakeholders, socio-economic and environmental aspects, regulations, policies and standards (ISO 2009; ISO 2002).

For instance, hospitals would not accept a risk of surgical instrument being retained in a patient's body after a surgical procedure since there is a national requirement for the prevention of this event. Here, this requirement can be determined as one of the risk criteria.

Decisions regarding risk tolerability are often made through the use of risk matrices. Different bands on the risk matrix are used to support decision-making. For instance, for a risk matrix with three band, an upper band represents intolerable risks, a middle band encourages the "*As Low As Reasonably Practicable (ALARP)*" principle, and a lower band represents negligible risks (BSI 2010). However, there might also be some other aspects to take into account when deciding on the tolerability of risks including psychological, societal, moral, emotional, political and financial aspects (Suddle 2009).

The Office of Rail Regulation (ORR) identifies three risk acceptance principles. These are: the application of codes of practice (e.g. standards and rules), comparison with similar reference system(s), and explicit risk level (ORR 2015). If risks are known and well understood, the application of codes of practice can be applicable (ISO 2015). If the system to be assessed is sufficiently similar to any other reference systems, the comparison with the similar reference system can be applicable. When the risks are not covered by these two acceptance principles, explicit risk level can be determined to make decisions in relation to risk acceptance (ORR 2015; RSSB 2014).

Regarding risk prioritisation, multiple factors may be relevant and need to be determined, including likelihood, consequence and detectability of a risk as well as vulnerability and speed of onset (or velocity) (COSO 2012). Vulnerability is explained as the degree to which a system is susceptible to or unable to cope with the risk (Parry et al. 2007). The higher the vulnerability, the greater the impact of the risk event. Speed of onset (or velocity) refers how quickly a risk event manifests itself (COSO 2012). To measure risk priority by combining these factors, a nominal measurement scale for each factor can be used; an example is given in Table 2.3

Table 2.3 Nominal measurement scales to assess risks

Score	Consequence	Likelihood	Detectability	Vulnerability	Speed of Onset
1	Negligible	Rare	Very high	Very low	Very low
2	Minor	Unlikely	High	Low	Low
3	Moderate	Possible	Medium	Medium	Medium
4	Major	Likely	Low	High	High
5	Extreme	Frequent	Very low	Very high	Very High

While measurements such as those in Table 2.3 provide valuable insights into the criticality of a risk, the factors that influence the decisions made on the tolerability of a risk also play an essential role in prioritising risks.

2.6.3 POST RISK ASSESSMENT PRACTICE

After risk evaluation, the last step in risk assessment, risk treatment options are considered. Risk treatment involves the selection and implementation of one or more options to modify risk. These options include avoiding the risk, taking the risk to pursue an opportunity, removing the risk source, changing the likelihood, changing the consequence, sharing the risk with other parties and retaining the risk (BSI 2010).

Additionally, the BS EN 31010, Risk Management Standard, states that findings of the risk assessment should be documented. The documentation of assessed risks should include assessment objectives, an assessment of scope, a system description, context, risk criteria, risk assessment methodology, sources, assessment results, discussions, recommended actions, a follow-up review time schedule and references (BSI 2010).

Good overall risk assessment practice not only considers the risk assessment process steps, it also takes into account prior, and post risk assessment activities. However, it should be noted that different industries might need to adjust some of these elements based on their needs and capacity. Additionally, the success of the practice relies on assessors' knowledge and skills, organisational culture and

multiple other factors (e.g. using the right techniques, involving appropriate people and implementing recommended actions).

2.7 DISCUSSION

The findings of this chapter demonstrate that safety in healthcare needs to be improved despite significant efforts. Although some safety interventions have already been adopted to promote safety (Illingworth 2015b; Vincent et al. 2013), these applications have been found to be limited in their effectiveness (Dixon-Woods and Pronovost 2016) and predominantly focused on reactive approaches after harm occurs (Sujan et al. 2015). Therefore, this research defines the first gap as:

There has been a lack of proactive applications to ensure safety in healthcare.

Risk assessment, however, is a proactive application to ensure safety. While risk assessment is already utilised in healthcare, current risk assessment practice has been argued to be insufficient and a number of weaknesses have already been defined. For instance, there is a lack of clarity about how to express risks and how to use risk assessment as a tool to improve patient safety (Eidesen et al. 2009); only few risk assessment techniques used (Gray and Cohen 2012; Vincent et al. 2013; Ward et al. 2010); and biased risk estimations are often made (Card et al. 2013; Gadd et al. 2003). All these challenges lead to the second gap:

There is a need to improve current risk assessment practice.

This need can be responded to both by considering existing challenges as well as introducing the missing elements for good risk assessment practice. The challenges, for instance, could be addressed by a number of recommendations. Safety culture could be improved to encourage the involvement of more staff in risk management (Kuhn and Youngberg 2002). Staff skills/knowledge could be improved in the area of risk assessment to implement risk assessment more

effectively (Card et al. 2014b). A risk communication tool could be developed for the use of high-level stakeholders as in regulators and the healthcare organisations (Sujan et al. 2016).

Additionally, a number of proactive hazard analysis techniques could be transferred from safety-critical industries (DeRosier et al. 2002). Although, specific tools and techniques from other industries may not easily transfer into healthcare, the principles behind them could be (Vincent et al. 2014). Michie *et al.* (2005) claim that better healthcare outcomes might be achieved through providing theoretical understanding of the processes that relate to behaviour change of the healthcare professionals (Michie et al. 2005).

Mullai (2006) also highlights the importance of the understanding of risk management in the first place to manage risks. Moreover, a widely known risk management standard, BS ISO 31000 (2011), explains that successful risk management practice depends on the effectiveness of the risk management framework in providing adequate foundations. Therefore, this research focuses on the design of a risk assessment approach to support healthcare staff in risk assessment by learning from prescribed good risk assessment practices of safety-critical industries.

To design such an approach, the general principles behind risk assessment practice should be considered. Since risk assessment is built on accident models and sequential accident models are criticised by researchers, this research assumes that accidents result from several contributing factors arising from different levels of the system (Underwood and Waterson 2014). Therefore, this research determines multiple contributing factors rather than seeking a cause and effect relationship.

The research takes a further step and includes in its scope the improvement of risk assessment practices in hospitals in NHS England. This is due to the fact that hospitals are complex, an enormous number of incidents occur in hospitals, and hospitals have the highest healthcare spending and employ a large number of staff (Davies 2014; Vincent and Amalberti 2016).

It should be also noted that risk assessment is not a stand-alone activity, and it is part of a larger system (e.g. quality and safety management). Thus, any behaviour change in the linkages and interactions of the parts influences the entire system (Dekker and Leveson 2015). Effective risk assessment practice, therefore, requires additional considerations prior to, during and after the assessment (HSE 2006b). However, there is little evidence which establish how risks are assessed in hospitals and whether hospitals practice the fundamental elements of good risk assessment. While there have been some attempts to conduct risk related studies, they remained in focus on particular steps of the risk assessment or on the assessment of specific risks. For instance, it is often clinical risks such as venous thromboembolism (VTE) (Wilson 2015) and falls (Saverino et al. 2015) assessed. Simsekler (2014) developed a risk identification framework. However, his framework remains conceptual and, therefore, it helps little to the real-life scenarios by itself. Card (2013) focused on risk control and provided practical ways of generating options for active risk control. However, risk control is a follow-up step of the risk assessment. This research thus attempts to investigate current practice in hospitals, identifies the problems involved in it, and proposes an improved risk assessment approach.

The main research question that drives this thesis is: *How can current risk assessment practice be improved to ensure safety in hospitals?*

To investigate this main research question, a set of questions was derived from the preliminary evidence gathered in this chapter. These questions fall into three general categories: prescribed good practice, current practice in hospitals and proposed risk assessment practice.

Prescribed good practice:

RQ1: What is prescribed good practice in risk assessment?

Current practice in hospitals:

RQ2: How is current risk assessment performed in hospitals?

RQ3: What are the problems with current risk assessment practice in hospitals?

Proposed practice:

RQ4: How would good risk assessment practice be tailored to hospitals?

RQ5: What views do healthcare staff have on the proposed risk assessment practice?

The first category, *prescribed good practice*, aims to reveal a clear understanding of what good risk assessment practice constitutes by addressing RQ1. The second category, *current practice*, is designed to investigate current risk assessment practice in hospitals by addressing RQ2 and RQ3. The third category, *proposed practice*, seeks to translate good practice applications to current risk assessment practice in hospitals through addressing RQ4 and RQ5.

In this research, while this chapter addressed the RQ1 through the review of a large number of international and national risk assessment standards, it did not provide much evidence regarding current risk assessment practice. Therefore, more evidence will be collected to understand the practical applications of risk assessment in hospitals in NHS England. In so doing, RQ2 and RQ3 are explored in Chapter 2, 4 and 5; and RQ4 and RQ5 are addressed in Chapter 6 and 7.

2.8 SUMMARY

This chapter examined existing literature on safety, accidents, and risk assessment practice. In addition, this chapter identified gaps in the literature in order to introduce areas for further research. The literature published, so far, predominantly focuses on safety after harm occurs and pays less attention to risk assessment to prevent harm in the first place. Indeed, there is a lack of research providing an understanding of current risk assessment practice in hospitals. However, there have been a number of challenges identified regarding the current risk assessment practice in hospitals, which indicates that there is

potential to improve current risk assessment practice. Therefore, this research first investigates current risk assessment practice and, then, proposes a new risk assessment approach by building on the general principles behind risk assessment.

CHAPTER 3

RESEARCH PROCESS

3.1 INTRODUCTION TO THE RESEARCH PROCESS

The previous chapter identified gaps and limitations in the existing literature on risk assessment, from which the research questions emerged. This chapter presents an overview of the process taken in this research by following a research process framework as in Figure 3.1 (Sim and Wright 2002).

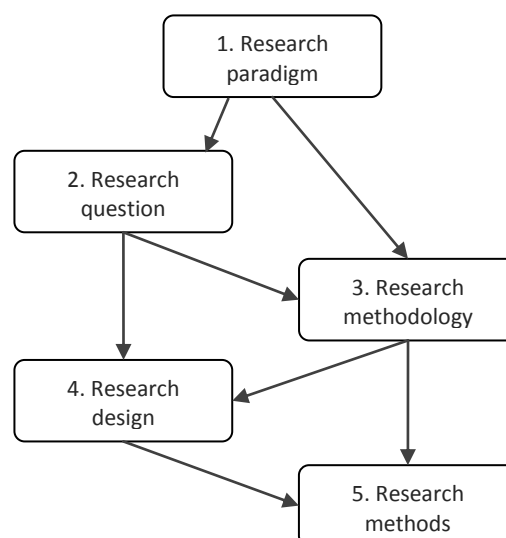


Figure 3.1 Relationships between research process components adapted from Sim and Wright (2002)

Firstly, this chapter provides an introduction to research paradigms and their influence on this research. Following that the research questions are presented again, the methodological approach is explained, the research design is outlined and the methods to be employed in this research to address research questions are outlined. Lastly, ethical considerations taken in this research are explained.

3.2 RESEARCH PARADIGM

Guba (1990) defined paradigms as *“a basic set of beliefs that guides action, whether of the everyday garden variety or action taken in connection with a disciplined inquiry”*. A research paradigm guides researchers by providing directions in the research process. Guba (1990) classifies research paradigms into four categories: positivism, post-positivism, critical theory and constructivism. Each paradigm is characterised by the way it responds to three fundamental questions. These are: (1) ontological, by asking *“What is the nature of the knowable?”*, (2) epistemological, by asking *“What is the nature of the relationship between the inquirer and the known?”* and (3) methodological, by asking *“How should the inquirer go about finding out knowledge?”* (Guba 1990) Table 3.1 illustrates these four paradigms with their characteristics.

Table 3.1 Characteristics of research paradigm adapted from Guba (1990)

Paradigm Classification	Paradigm Characteristics		
	Ontological	Epistemological	Methodological
Positivism	Realism	Objectivism	Experimental/ manipulative
Post-positivism	Critical realism	Modified objectivism	Modified experimental/ manipulative
Critical theory	Critical realism	Subjectivism	Dialogical, transformative
Constructivism	Relativism	Subjectivism	Hermeneutic, dialectic

Positivism is based on reality by looking for *“How things really work”* (Guba 1990). The role of the researcher is to test theories and to contribute to the

development of laws. Natural science studies often follow a positivist approach (Bryman 2001). Post-positivism is a modified version of positivism by still looking for reality but by considering the fact that it is impossible for humans to perceive the entire true reality. Critical theory is based on critical realism (reality exists, but can never be fully apprehended), but with a subjectivist approach by considering the values that mediate inquiry. Constructivism is also a subjectivist approach which assumes that reality can change depending on the perception of knowledge, and constructivism rejects the use of natural science methods to view truths about the social world (Guba 1990; Robson 2002).

Much research in social science uses critical realism to provide an appropriate framework for designing real world studies (Robson 2002). The research presented here accepts that reality is out there, however it can be difficult to see it as it is. This was due to the fact that the current risk assessment practice was not known well and observations can be fallible. Different individuals might understand and apply risk assessment differently. Therefore, this research also fits closer with critical realism and modified objectivism, which falls under post-positivism paradigm. Indeed, this research does not aim to test a theory and rejects the use of natural science methods to reveal truths; it aims instead to understand the current risk assessment practice and to improve it. To reveal reality more objectively, triangulation of sources is used.

In the next section, research questions are listed, which are drawn from the primary conclusions of the literature review.

3.3 RESEARCH QUESTIONS

As introduced in Section 2.7.1, this research primarily explores the following question:

How can current risk assessment practice be improved to ensure safety in hospitals?

In addition to this, the following five additional research questions were derived and are elaborated throughout the current research.

1. What is prescribed good practice in risk assessment?
2. How is current risk assessment performed in hospitals?
3. What are the problems with current risk assessment practice in hospitals?
4. How would good risk assessment practice be tailored to hospitals?
5. What views do healthcare staff have on the proposed risk assessment practice?

3.4 RESEARCH METHODOLOGY

Methodology is the overall approach to research. It refers to the general principles of investigation, which are based on underlying theoretical and philosophical assumptions (Sim and Wright 2002). Thus, the selection of a research methodology influences the effectiveness of the scientific research to achieve its aims (Blessing and Chakrabarti 2009; Eckert et al. 2003).

Since this research aims to design a better risk assessment approach in hospitals to improve safety, this research is considered to be design research. Therefore, design research methodologies were sought to find the most suitable methodology for this research. Since DRM is a commonly accepted methodology in design research including healthcare design research (Jafri 2010; Beniuk 2012; Simsekler 2014; Eckert et al. 2003), it is adopted as a core methodology in this research.

DRM is developed by Blessing *et al.* in 1992 to support design researchers by providing a rigorous approach (Blessing et al. 1992). The DRM provides an appropriate framework to address the current research questions. The DRM framework consists of four stages: research clarification, descriptive study I, prescriptive study and descriptive study II (Blessing and Chakrabarti 2009). Figure 3.2 illustrates the relationships between the DRM stages, their basic meanings, and their main outcomes.

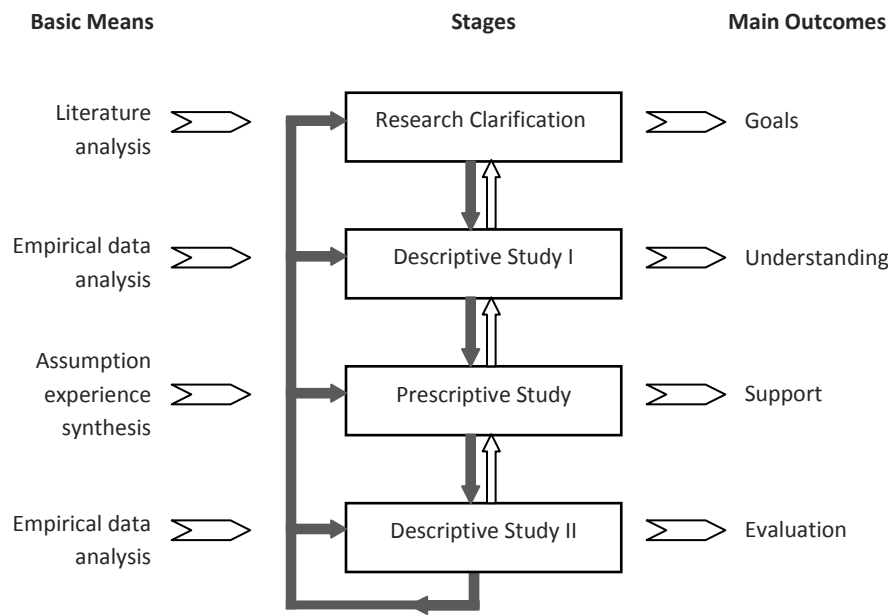


Figure 3.2 The DRM framework Blessing and Chakrabarti (2009)

In the Research Clarification (RC) stage, researchers aim to find some evidence to formulate a realistic and worthwhile research goal primarily through a literature search. This stage develops an initial description of the existing and desired situation, formulates criteria to measure the success of the research, and provides an overall research plan (i.e. focus, goals, problems, research questions, approach and expected contribution) (Blessing and Chakrabarti 2009).

In the Descriptive Study I (DS-I) stage, researchers analyse the existing process further to elaborate the initial description of the current situation, to identify current problems and to identify factors that influence its success. This stage provides a basis for the development of the existing design (Blessing and Chakrabarti 2009).

In the Prescriptive Study (PS) stage, researchers describe the desired situation utilising their increased understanding of the existing situation. They develop a model or theory to describe the desired situation (Blessing and Chakrabarti 2009).

In the Descriptive Study II (DS-II) stage, researchers evaluate their developed model or theory in terms of whether it functions as intended. Additionally, the

model or theory is evaluated by considering its impact, applicability and usefulness based on the success criteria that they developed in the Research Clarification stage (Blessing and Chakrabarti 2009). While each step has been explained in sequence, DRM allows iterations to improve the understanding and efficiency of the design process (Chakrabarti et al. 2004). Researchers also revealed the need for iterations within each design research stage as well as between different stages (Antonsson 1987; Reich 1995). However, it is also recommended to plan stages in order to avoid too many unexpected iterations.

DRM gives a goal-directed and flexible approach to allow researchers adjust the DRM framework steps based on the needs of the research topic instead of strictly following a step by step approach. Indeed, researchers following a design methodology with a goal-directed and flexible approach were found to produce a higher quality of design than those following a step by step approach (Fricke 1993).

Table 3.2 Types of design research with the DRM framework Blessing and Chakrabarti (2009)

Research Clarification	Descriptive Study I	Prescriptive Study	Descriptive Study II
1. Review-based	Comprehensive		
2. Review-based	Comprehensive	Initial	
3. Review-based	Review-based	Comprehensive	Initial
4. Review-based	Review-based	Review-based Initial/ Comprehensive	Comprehensive
5. Review-based	Comprehensive	Comprehensive	Initial
6. Review-based	Review-based	Comprehensive	Comprehensive
7. Review-based	Comprehensive	Comprehensive	Comprehensive

Blessing and Chakrabarti (2009) identified seven potential design research types through the use of the DRM framework. Table 3.2 lists these research types by considering whether a particular research stage requires a review-based, a comprehensive or an initial study. A review-based study only focuses on the

literature review. A comprehensive study includes both a literature review and other studies through which the researcher produces results (e.g. empirical study). An initial study provides initial results for the use of other researchers (Blessing and Chakrabarti 2009). This research project most closely sits with Type 5, which is called *Development of Support Based on a Comprehensive Study of the Existing Situation*. Design-related PhD studies often aim for Type 5 and 6, but end up with Type 2 and 3 (Blessing and Chakrabarti 2009). In this current research, Type 6 could not be performed due to feasibility and time constraints. However, an initial investigation could be completed in the Descriptive Study II stage, and so the research falls under Type 5.

While this research used the DRM framework, this study could have used other methodologies. For instance, healthcare-specific methodologies could have been used. Of these other methodologies, the Plan Do Study Act (PDSA) cycle is widely used in healthcare for quality improvement (Varkey et al. 2007), a participatory approach has been used in healthcare for establishing consensus between different stakeholders for an integrated care programme (Eyre et al. 2017), and a system-based user-centred approach has been used for designing healthcare (Clarkson et al. 2004). However, the PDSA method tends to be oversimplified by its users in healthcare (Reed and Card 2016), and it does not allow iterations between adjacent steps whereas design studies often require iterations. A participatory approach is also mentioned within the context of healthcare improvement methodologies; however, it is not a research methodology by itself since it does not provide any guidance on how to carry out a research study. While a system-based user-centred approach could have been applicable in this research, the DRM framework also follows similar paths in terms of understanding the needs, developing potential solutions, and implementing and evaluating the proposed solutions. Additionally, most of the healthcare methodologies are used for specific clinical studies whereas this research is about the design of a new risk assessment approach. Thus, this research selected the use of DRM.

However, while the DRM framework provides good guidance on how to conduct design research, it does not provide methods to be used (Blessing and Chakrabarti 2009). It needs to be tailored to each research project and suitable methods should be selected to apply the research methodology. The following section explains the research design and methods selected for this research study.

3.5 RESEARCH DESIGN AND METHODS

A research design provides structured guidance for data collection and analysis in order to address the research questions (Bryman 2001; Sim and Wright 2002). This research is designed on the overall research methodology by employing research methods given in Table 3.3, which lists the methods employed in relation to the DRM stages, research questions and chapters.

In the Research Clarification stage, documents were reviewed to justify the necessity of the research, to provide a basic understanding of the research topic and to design the research questions.

Since the Descriptive Study I seeks to provide a deep understanding of the current risk assessment practice in hospitals, hospitals' risk assessment documents were reviewed to understand the recommended practice. Additionally, interviews and questionnaires were conducted to understand the practical experience of NHS staff in conducting risk assessments.

As the Prescriptive Study proposes a new approach, documents were reviewed to describe the good prescribed risk assessment practice and group discussions were made to help the design of the proposed approach.

Table 3.3 Research design and methods

Research Methodology Stages	Research Questions	Chapters	Methods				
			Document analysis	Interviews	Questionnaires	Group discussions	Case study
Research clarification		1, 2, 3	✓				
Descriptive study I	What is prescribed good practice in risk assessment?	2	✓				
	How is current risk assessment performed in hospitals?	2, 4, 5	✓	✓	✓		
	What are the problems with current risk assessment practice in hospitals?	2, 4, 5	✓	✓	✓		
Prescriptive study	How would good risk assessment practice be tailored to hospitals?	6	✓			✓	
Descriptive study II	What views do healthcare staff have on the proposed risk assessment practice?	7		✓	✓	✓	✓

In the Descriptive Study II, interviews and questionnaires were conducted to ensure that the proposed practice satisfies its potential users, and group discussions and a case study were conducted to evaluate the proposed approach.

Overall, a variety of methods were selected to collect data and to evaluate the findings. Document analysis was conducted to reveal the described risk assessment practice. Interviews and questionnaires were conducted to understand the practical experience of healthcare staff on risk assessment as well as to evaluate the proposed risk assessment approach. Group discussions and a case study were conducted to design and evaluate the proposed approach.

While a number of methods were selected to conduct this research, multiple other methods could have also been used such as ethnography, control studies, and workshops. As a result, the research could have provided a better understanding of the current risk assessment practice, and the proposed approach could have been evaluated more reliably. For instance, ethnography could reveal the culture of risk assessment practice in hospitals; and control

studies and workshops could provide a more reliable evaluation of the proposed risk assessment approach. However, such methods could not have been used in this research due to the limited time availability of healthcare staff and their unwillingness to be involved in the research study. Additionally, these methods might still not provide as much information as received from interviews.

A brief description is provided for each method below while more details can be found in the relevant chapter.

3.5.1 DOCUMENT ANALYSIS

The documentation of personal (e.g. letters and photographs) and impersonal (e.g. public inquiries, internet sources and organisational documents) data are valuable sources for researchers (Bryman 2001; Grbich 1999). Documents not only provide data on the research context but also can be used to verify findings from other sources.

For this research, documentation data sources include incident and risk records, official reports, hospitals' risk assessment policies, procedures and strategies, hospital board meeting notes, academic journals, and national and international risk management standards.

Document analysis mainly involves three steps: skimming (superficial examination), reading and interpretation (Bowen 2009). All chapters, except Chapter 7, conducted document analysis to support evidence collected in relation to the understanding of current and proposed practices. In Chapter 4, especially, a detailed document analysis was conducted through a Freedom of Information (FOI) request of the risk assessment policies and procedures. However, document analysis alone may not reveal the practical experience of the healthcare staff in risk assessment (see section 4.4). Therefore, this study also uses other methods to understand actual practice, including interviews and questionnaires.

3.5.2 INTERVIEW

Interviewing helps researchers gain information in relation to the perspectives, understanding and experience of people on a specific topic (Grbich 1999). Interviews can be structured, semi-structured or unstructured. Structured interviews tend to be used in quantitative research whereas semi-structured and unstructured interviews tend to be preferred in qualitative research (Bryman 2001). In a structured interview, the interviewer lists questions and asks the same questions to each interviewee in the same sequence (Grbich 1999). In a semi-structured interview, the interviewer does not have to follow the same sequence or ask the same questions. In an unstructured interview, the interviewer starts by asking a single question and the rest depends on the nature of the conversation (Bryman 2001).

Since this study seeks to understand the perceptions of people involved in current risk assessment practice, interviews were conducted to reveal the practical experience of the healthcare staff. In hospitals, healthcare staff with different professions and experience might conduct risk assessments differently. Thus, unstructured and semi-structured interviews were conducted to be able to adjust questions depending on the responses. Unstructured interviews, detailed in Chapter 5, were used to gain an understanding of current risk assessment practice through having a natural conversation with the interviewees. Semi-structured interviews, found in Chapter 5 and 7, were designed to reveal the practical experience of healthcare staff in risk assessment and to evaluate the proposed risk assessment approach. Due to the time constraints of the healthcare staff, participation in interviews was limited. Consequently, the findings from interviews can only reflect the views of participants (see section 5.2.4.5). To mitigate the effects of such a limitation, a questionnaire that minimises time requirements for participation was also administered.

3.5.3 QUESTIONNAIRE

Questionnaires are frequently used in social and health research to collect data (Sim and Wright 2002). Conducting a questionnaire helps researchers collect data regarding beliefs, opinions, or reasons for an event or facts through asking questions (Blessing and Chakrabarti 2009). These questions can be both open-ended and closed-ended. Open-ended questions allow participants to respond in his/her words. Closed-ended questions provide a list of predetermined responses from which the participants pick the one that most closely represents their opinions (Sim and Wright 2002).

This research uses questionnaires to collect data since completing a short questionnaire with well-formulated questions would save time for both the researcher and participants. In Chapter 5, a questionnaire with an electronic and paper-based version was designed to understand current risk assessment practice. In Chapter 7, a paper-based questionnaire was designed to evaluate the proposed framework. Both questionnaires have open-ended and closed-ended questions to direct participants with predetermined responses as well as to give them the flexibility to respond in their own words.

However, it should be noted that questionnaires also have limitations. For example, the questionnaires within this research have limits since they did not provide duplicating and reversing questions (see Chapter 5 and 7). As a result, it might have led to verification bias in the study and participants might have responded the questions in favour of the research.

3.5.4 GROUP DISCUSSION

Group discussion is also a method of collecting data from multiple people (Pope and Mays 2006). Smaller scaled groups lead to a better use of group discussions (Payne and Payne 2004). Group discussions can generate a large amount of data with many critical comments on the topic to be discussed (Pope and Mays 2006). The speed and practicality of a group discussion increases the value of group discussion as a research method (Payne and Payne 2004).

For this research, group discussion was made at all stages of the research through meetings with three researchers including the researcher and two supervisors. It was conducted to enhance the validity of the research findings instead of collecting data. Particularly, group discussions were held to develop and evaluate the proposed approach. In turn, the researcher made continuous improvements based on these discussions.

3.5.5 CASE STUDY

A case study entails a detailed analysis of a single case (Bryman 2001). It aims to describe a problem, to build a solution, to interpret the solution critically or to build a theory (Yin 1993). Stake (1995) divides case studies into three categories: (1) intrinsic to have a better understanding of a particular case, (2) instrumental to use the case to gain a greater understanding of a theory or issue, and (3) collective to use multiple cases to gain a greater understanding of a theory or issue (Stake 1995).

In this research, an instrumental case study was conducted in Chapter 7 in combination with interviews to give an example of the use of the proposed approach.

3.6 ETHICAL CONSIDERATIONS

In most research, there are ethical and legal considerations that must be addressed in conducting the study. The ethical considerations require that participants should not be harmed due to their participation in the research, and that they should give their informed consent for their involvement (Bowling 2002). Sim and Wright (2002) list central issues in research ethics as informed consent, privacy and confidentiality, anonymity, deception, risk of harm and exploitation.

Healthcare staff from different professions and Trusts participated in this research, and their participation was voluntary. Since this research involves participants from multiple Trusts in NHS England, the researcher obtained Health Research Authority (HRA) approval (see Appendix 2).

The obtainment of HRA approval required lots of efforts and it took approximately 6 months. 1 month required to complete and revise the necessary documents. Following that it took around 2 months to receive peer review comments from the Research and Development Department at the Cambridge University Hospitals (CUH) NHS Foundation since they were the sponsor of this research study. After making necessary changes based on the comments given, an application was submitted to gain HRA approval. HRA approval comprised a review by an NHS Research Ethics Committee (REC) on behalf of the participating organisations. It took almost 3 months for the NHS REC to approve this research study without giving any changes. The REC reference of this study is 16/HRA/4955.

After obtaining the HRA approval, a confirmation of capacity and capability of the nine participating Trusts were received by email in order to conduct the study on the sites of these Trusts. So, while nine Trusts were involved in this study, participants of this study were not limited to these nine Trusts.

Furthermore, a letter of access was gained from the CUH NHS Foundation Trust through the application of a research passport, which took 1 month to gain (see Appendix 3). This approval was obtained to access hospitals' risk register and incident reporting systems.

Returning to the central issues of research ethics, informed consent was obtained from each participant either verbally prior to their participation or as a signed form; all data were analysed anonymously; participants were informed about the research study; and participants were informed that they could withdraw their participation at any point.

3.7 SUMMARY

This chapter presented an overview of the research process employed in this research. The research paradigm adopted here is post-positivism: accepting that there is a reality, but one that may never fully be apprehended. Therefore, different sources were used to identify the reality as closely as possible. The Design Research Methodology was selected as it is widely used in the design research field and successfully applied in the healthcare research field. This chapter then introduced the methods that were selected to address the research questions. The following chapters put this research methodology into practice to reveal the existing situation in more detail so as to investigate potential areas for improvement in risk assessment practice in hospitals.

CHAPTER 4

RECOMMENDED RISK ASSESSMENT PRACTICE IN HOSPITALS IN NHS ENGLAND

4.1 INTRODUCTION TO RECOMMENDED PRACTICE

Given the lack of substantial literature detailing current risk assessment practice in hospitals in NHS England, this chapter investigates the current recommended risk assessment practice to explore '*work as described*'. To do so, this chapter clarifies the recommended risk assessment practice in hospitals in NHS England, and asks whether there is a need for improvements, and if so, what the potential improvements might be. In turn, the two research questions (RQ2 and RQ3) are partially addressed and evidence is provided for the main research question: "*How can current risk assessment practice be improved to ensure safety in hospitals?*".

4.2 METHODS

Document analysis was conducted by collecting risk assessment documents from each NHS England Acute Trust. To obtain data, a Freedom of Information Act 2000 (FOI) request was sent to all NHS England Acute Trusts (n=160) on July 11, 2016, by e-mail. The hospitals were asked to provide their current risk assessment procedure and policy (or nearest equivalent documents, e.g. risk management policy, strategy, procedure or guidance). Once the request is received by hospitals, hospitals aim to respond to the request within 20 working days (NHS England 2000).

Collected documents were analysed to explore the recommended risk assessment practice. In so doing, documents were initially reviewed to determine how risk terminology is defined, how risks are assessed, and what guidance is provided on risk assessment. In the second review, existing challenges were identified by considering the findings from documents and good risk assessment practice. Following that, potential areas for improvement were recommended.

4.3 RESULTS

62.5 percent of hospitals (100) responded within 35 working days following the FOI request. From these responses, 142 documents (4190 pages) were collated. The majority of the hospitals (66) provided only one document, and the maximum number of documents provided by a single hospital was four documents.

Most of the collected documents were titled as risk assessment (or risk management) policy, strategy or procedure. Other documents were also received, including risk assessment guidance, incident reporting policy, risk handbook, and health and safety policy.

4.3.1 RISK TERMINOLOGY

A review of the collected documents revealed that a variety of definitions are provided for the term *risk* and *risk assessment*. Results show that 87 out of 100 hospitals provided a definition for the term *risk*. Among these definitions, the majority (63) defined risk to be something negative such as a “*potential adverse event*”, “*threat to objectives*”, “*potential harm*” or “*potential harm, loss or damage*”. The remainder (37), however, described risk in more neutral terms such as “*an event*”, “*uncertainty on objectives*” or “*an uncertain outcome*” which may result in either positive or negative consequences. Table 4.1 presents these definitions in more detail.

Table 4.1 Characteristics of the provided risk definitions

Risk Description	Number of Hospitals
Event	
Neutral	1
Negative (e.g. adverse event and unfavourable event)	16
Impact on objectives	
Neutral (i.e. ISO risk definition)	32
Negative (e.g. threat to objectives)	9
Harm	11
Harm, loss or damage	14
Uncertainty of outcome	4

However, it should be noted that most of the given risk definitions (32) used the ISO Risk Management Standard definition of “*the effect of uncertainty on objectives*” or similar. Indeed, 31 hospitals cited well-known risk management standards (e.g. AS/NZA 4360:1999, ISO 31000:2009 and ISO 31100) in their documents. Furthermore, 55 hospitals provided a clear definition for the term *risk assessment*. Risk assessment was often defined as either “*an examination of a potential risk*”, or “*a systematic process of assessing the likelihood of something happening and its potential consequence*”. Yet, few hospitals provided clear definitions for all risk assessment terms in their documents.

Although healthcare staff may not always be using these documents in their daily risk assessment practices, these collected documents are intended to guide them.

Therefore, clear terminology in such documents may help understand the risk assessment practice better. However, the majority of the hospitals clearly described two types of risks, namely operational and strategic risks. Both clinical and non-clinical risks can be defined under the umbrella of these two types. Representative definitions are provided below:

Operational risks are defined as:

“by-products of the day to day running of a trust and include a broad spectrum of risks including clinical risks, fraud risk, financial risk, legal risks arising from employment law or health and safety legislation and risks of damage to assets or systems failures.” (pg4, Risk Management Policy and Guidance, University Hospitals Bristol NHS Foundation Trust)

and strategic risks are identified as:



“representing a threat to achieving the Trust’s strategic objectives or to its continued existence.” (pg4, Risk Management Policy and Guidance, University Hospitals Bristol NHS Foundation Trust)

The front-line staff assess operational risks and the board-level staff assess strategic risks. Operational risks are assessed in a bottom-up manner from front-line staff to board-level staff and are registered in the Trusts’ risk register systems. Conversely, strategic risks are assessed top-down and stated on the Board Assurance Framework (BAF), which is a document that gathers information in relation to the strategic risks. The front-line staff often assess operational risks, and if they cannot manage these risks, they are escalated to a higher managerial level. Consequently, some of the operational risks can be escalated to the board-level and such risks can be treated as strategic risks. The board-level, in general, identifies strategic risks, and informs the lower-level staff of these strategic risks, if necessary.

4.3.2 RISK ASSESSMENT PRACTICE

Findings from the collected documents show that risk assessment generally involves the identification of risk, the measurement of the level of risk by multiplying the likelihood and consequence scores, the prioritisation of risk through the use of risk matrices, and the determination of the required actions to manage these risks. In so doing, each hospital provides a standard risk assessment template, which is either available electronically on the risk register system or manually as a form. Hospitals also provide various risk assessment forms for the assessment of specific types of risks such as stress risk assessment, moving and handling, and new and expectant mother risk assessment forms.

Table 4.2 Recommended tools and techniques to support risk assessment

Techniques and Tools	Number of Hospitals Cited	Risk Identification	Risk Analysis	Risk Evaluation
Audit	100	✓	✓	✓
Risk registers	100	✓	✓	✓
Incident reporting	100	✓	✓	✓
Heat map/ risk matrix	99		✓	✓
Root Cause Analysis	52	✓	✓	✓
Checklist	38	✓		
Whistle blowing	33	✓	✓	✓
Walk-around/ walk about	29	✓		
Horizon scanning	20	✓	✓	
Benchmarking	15	✓	✓	
SWOT	7	✓		
Brainstorming/ mind storming	5	✓		
PEST/PESTLE analysis	5	✓		
Decision tree	3		✓	
Grapevine/ intuition	2	✓		
Lean analysis	2	✓	✓	✓
FMEA	1	✓	✓	✓
Bow-tie analysis	1		✓	✓
Event tree analysis	1	✓	✓	
Fault tree analysis	1	✓	✓	
 : Strongly Applicable,  : Applicable				

The collected documents also revealed that hospitals recommend the use of a number of techniques to support risk assessment practice. Table 4.2 lists all the tools and techniques except specific risk assessment forms that were mentioned in these documents, and shows to which risk assessment step these tools could

be applicable (see Appendix 4 for a brief summary of each tool and technique). The decisions on the applicability of these tools on the risk assessment steps were made by reviewing the British Standards (BSI 2010) on risk assessment techniques in conjunction with discussions with the research team and a risk manager from an acute specialist hospital.

As Table 4.2 indicates, almost all hospitals recommend audits, risk registers, incident reporting and risk matrices to support risk assessment practice. Other techniques were widely mentioned to assess risks including checklists, whistle blowing, walk-arounds, horizon scanning and benchmarking. Furthermore, a few hospitals recommended the use of decision trees to support risk assessment, and a single hospital recommended the use of FMEA, the bow-tie analysis, event tree analysis and fault tree analysis.

However, it was recognised that some of these tools and techniques are not strongly applicable to conducting a full risk assessment. While almost all are applicable to identifying risks and most are applicable to analysing risks, the majority are not applicable to evaluating risks. These tools and techniques are therefore considered to support risk assessment rather than constituting risk assessment tools or techniques in themselves. For instance, risk registers were highlighted in each document to support risk assessment, and can even be applicable to all stages of risk assessment. However, they are a database to keep risk records. Indeed, risk registers are defined as *“a database that holds the main record of all identified risks to the trust’s objectives and operations.”* (pg 7, Risk Management Strategy and Policy, Aintree University Hospital NHS Foundation Trust).

It was clear from the reviewed documents that a central tool in hospital risk assessment practice is the use of risk matrices. Risk matrices were recommended to be used to determine the level of risk, to evaluate the tolerability of a risk, and to allocate resources for risk treatment. They were found to be embedded in the risk assessment system and, therefore, the efficiency of their use should have a strong influence on risk assessment performance. Therefore, the following section looks at risk matrices in more detail.

4.3.3 RISK MATRICES

Since risk matrices are core to organisation-wide risk assessment, the documents collected were reviewed to investigate the risk matrices currently being used. Findings revealed that 99 out of 100 hospitals provided a standard 5x5 risk matrix which consists of a consequence and likelihood axes. The consequence (C) axis was categorised with nominal descriptors, and a score from 1 to 5 is assigned for each descriptor as follows: *negligible*=1, *minor*=2, *moderate*=3, *major*=4 and *catastrophic*=5. Likewise, the likelihood (L) axis scale most often used was: *rare*=1, *unlikely*=2, *possible*=3, *likely*=4 and *almost certain*=5. Since a score is assigned to both consequence and likelihood, risk scores are estimated by multiplying consequence and likelihood scores to categorise the level of risk or risk rating (e.g. low, moderate, high and extreme) (Figure 4.1).

		Consequence				
		Negligible 1	Minor 2	Moderate 3	Major 4	Catastrophic 5
Likelihood	5 Almost certain	Moderate 5	High 10	Extreme 15	Extreme 20	Extreme 25
	4 Likely	Moderate 4	High 8	High 12	Extreme 16	Extreme 20
	3 Possible	Low 3	Moderate 6	High 9	High 12	Extreme 15
	2 Unlikely	Low 2	Moderate 4	Moderate 6	High 8	High 10
	1 Rare	Low 1	Low 2	Low 3	Moderate 4	Moderate 5

Figure 4.1 A standard risk matrix

4.3.3.1 Characteristics of risk matrices

Figure 4.2 illustrates every type of risk matrix used and by how many hospitals. Each risk matrix type is identified with a unique code from M1 to M28. In total,

there were 28 different risk matrices defined, of which M9 was by far the most commonly used.

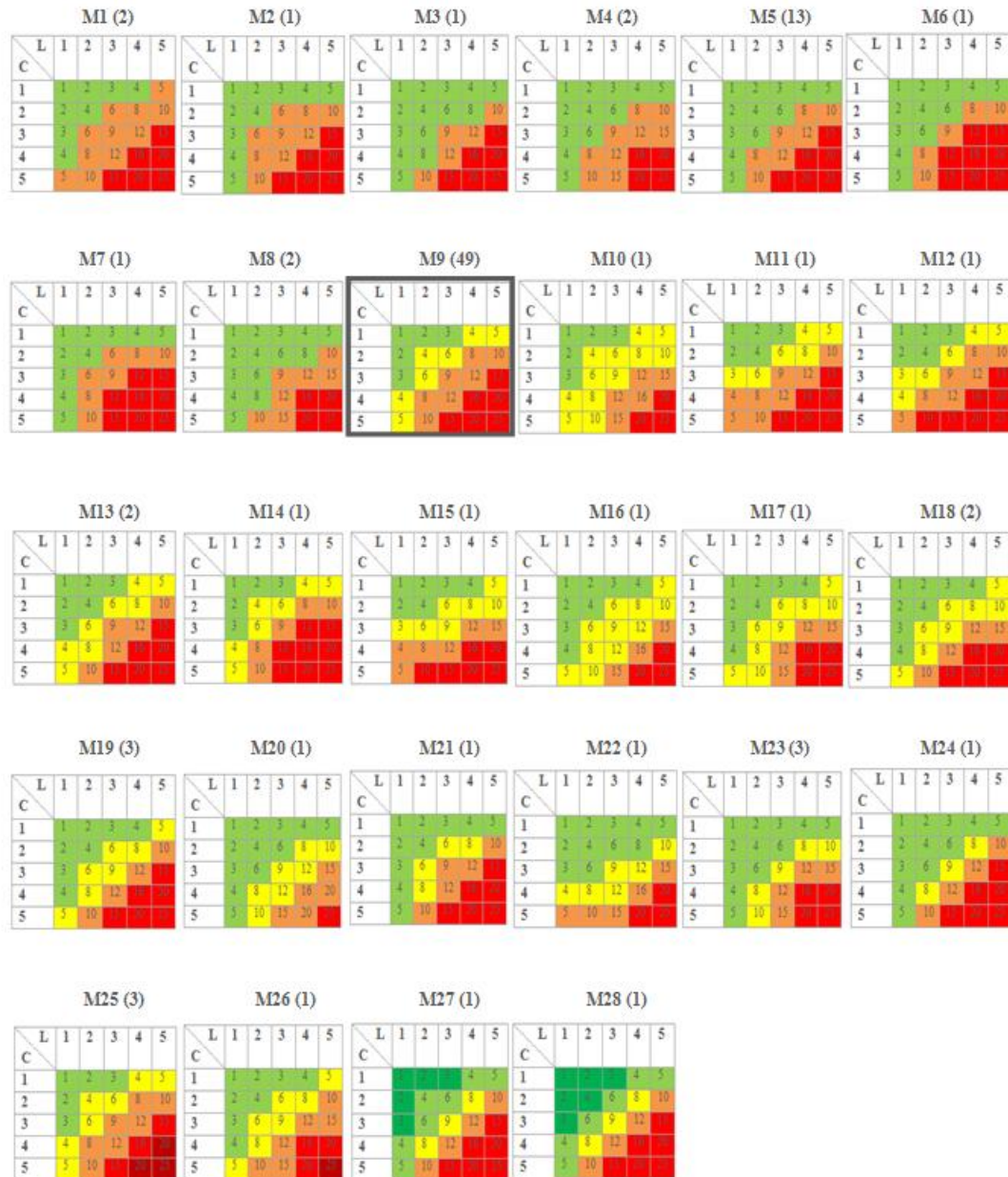


Figure 4.2 Risk matrix types (the number of acute trusts used)

Coloured bands represent the level of risk (risk rating) categories, the tolerability of a risk and the level of management action needed. For example, a green band (*a risk score of 1-3*) on the risk matrix of M9 represents low risk, a yellow band (*a risk score of 4-6*) represents moderate risk, an orange band (*a risk score of 8-12*) represents high risk, and a red band (*a risk score of 15-25*) represents extreme risk. Similarly, a risk matrix with three coloured bands categorises risk levels as

low, moderate and high; and one with five coloured bands categorises risk levels as very low, low, moderate, high and extreme. It was found that 23 percent use a risk matrix with three coloured bands, almost 71 percent use one with four coloured bands and 6 percent use one with five coloured bands.

Although coloured bands are used to determine the tolerability of a risk, only 28 percent of hospitals stated the link between band colour and risk tolerability on their policies and procedures. For instance, if M9 is used, a green band represents tolerable risks, a yellow band and an orange band represent undesirable risks and a red band represents intolerable risks. The majority of hospitals instead mentioned the acceptability of a risk; however, they did not provide much information on which risks were acceptable or which ones were not despite the fact that Trusts have a list of events which are not acceptable, called never events, and which include wrong site surgery, wrong route administration of medication and falls from poorly restricted windows (NHS England 2015a).

Additionally, the review of the collected dataset showed that nine hospitals use asymmetrical risk matrices, namely M11, M12, M13, M15, M18, M22 and M28. In an asymmetrical risk matrix, a risk score can be assigned to different risk levels. For instance, a risk score of 5 (L:5 x C:1 or L:1 x C:5) can be assigned both to moderate and high risk levels in risk matrix M11.

To determine the level of management action, hospitals provided guidance based on the coloured bands. The level of management action comprises the distribution of responsibilities, the determination of action prioritisation and the assignment of risk review frequency. Table 4.3 provides examples of this. However, the specific management actions can vary from hospital to hospital.

Table 4.3 Level of management action for each coloured band

Coloured Bands	Management Responsibility	Action Prioritisation	Review Frequency
3 Coloured bands			
Green band (Low)	Ward/ department	No immediate action required	Annually
Orange band (Moderate)	Division/ Directorate	Action required	Quarterly
Red band (High)	Board	Immediate action required	Monthly
4 Coloured bands			
Green band (Low)	Ward/ department	No immediate action required	Annually
Yellow band (Moderate)	Division	Action required	Quarterly
Orange band (High)	Directorate	Action required	Monthly
Red band (Extreme)	Board	Immediate action required	Monthly
5 Coloured bands			
Dark green band (Very low)	Ward/ department	No action required	Annually
Green band (Low)	Ward/ department	No immediate action required	Bi-annually
Yellow band (Moderate)	Division	Action required	Quarterly
Orange band (High)	Directorate	Action required	Monthly
Red band (Extreme)	Board	Immediate action required	Monthly

Hospitals may well provide different guidelines for scoring risks as well as different risk matrices, which may lead to a different decision being made on the management of the same risk, although it must be noted that their practical use may in any case differ from the recommendations.

4.3.3.2 Consequence and likelihood scoring guidance

All hospitals provided nominal descriptors to score consequence and likelihood (e.g. *negligible* and *minor*; *rare* and *unlikely*). However, although the majority of hospitals provided further guidance for scoring consequence and some for likelihood, none provided any justification for their recommended guidance.

85 out of 99 hospitals offered detailed guidance for scoring consequence, all of which were based on a single report, *A risk matrix for risk managers* (NPSA 2008). These hospitals provided explanations for each nominal descriptor by considering each consequence domain (i.e. impact on safety, quality, human resources, statutory requirements, reputation, business objectives, finance, service

interruption and the environment). For instance, a nominal descriptor of negligible is explained as “*minimal injury requiring no/minimal intervention or treatment*” by considering the consequence domain of impact on the safety (NPSA 2008).

In relation to the guidance provided for the likelihood scoring, this was provided in three different ways: (1) by explaining each score on a nominal descriptor (e.g. *L:1=rare and L:2=unlikely*), (2) by providing a time-based frequency scale (e.g. *L:1=not expected to occur for years, L:2=annually, L:3=monthly, L:4=weekly and L:5=daily*), and (3) by using probability (e.g. *L:1= <0.1% and L:5= >50%*). While almost all (96 out of 99) hospitals used a nominal descriptor, almost two in five (40) hospitals additionally provided time-based explanations, and slightly more (44) hospitals additionally provided probabilistic explanations of each score. However, only one in four (25) hospitals provided all these types of guidance, and no guidelines were provided relating to when to use nominal descriptor, time-based frequency scale or probability scale.

A variety of probability scoring guidance was provided alongside 12 different probability scoring schemes. For instance, a risk with the probability of 10% can be scored as 1 (*with the guidance of L:1=0-10%, L:2=11-30%, L:3=31-70%, L:4=71-90% and L:5=90-100% in the use of M9*) and yet in others can be scored as 5 (*with the guidance of L:1=1 in 100000, L:2=1 in 10000, L:3=1 in 1000, L:4=1 in 100 and L:5=1 in 10 in the use of M2*). Similarly, a risk with a probability of 50% can be scored as 5 in most of the hospitals, but can also be rated as 3 in a number of other hospitals.

Additionally, only sixteen hospitals provided further guidance in scoring a risk where there might be multiple potential consequences in the same consequence domain. To illustrate this concept, a risk of a patient falling on a ward could lead to outcomes of different severity: no harm (*C:1 x L:4*), minor cuts and bruises (*C:2 x L:3*), hip fracture (*C:4 x L:2*), or death (*C:5 x L:1*). Of those who provided guidance, five advised *the worst-case scenario* strategy; four advised *the highest risk score* strategy; one advised *the most likely scenario* strategy; and six advised *the reasonably foreseeable worst-case scenario* strategy. For example, following

the worst case scenario strategy would lead to death being determined, and, in turn, to a score of 5 ($C:5 \times L:1$); whereas following *the most likely scenario* strategy would lead to no harm being determined, and, in turn, to a score of 4 ($C:1 \times L:4$). Both, however, could lead to biased decisions being made on the management of risks.

4.4 DISCUSSION

The findings in this chapter show that most of the hospitals which responded consider risk as something negative (e.g. an adverse event or a threat to objectives), and few hospitals provided a clear description for all risk assessment terms (e.g. risk, hazard and risk assessment) in their policies and procedures. Although it is arguable whether hospitals need to explain every single risk term in their policies and procedures, providing a common understanding of terminology is considered to improve the effectiveness of risk assessment practice (Lyon and Hollcroft 2012). The problems with the misuse of risk terminology have been highlighted not only in healthcare but also in other industries (Aven 2012a; Aven 2010; Johansen and Rausand 2015; Mullai 2006). For instance, the terms of *risk* and *issue* have been interchangeably used (NHS England 2015c); and risk assessment can also be interchangeably used with risk management (Mullai 2006).

Although risk assessment terms were not clearly defined in these policies and procedures, the risk assessment process itself is explained in all documents. It was revealed that risk assessment is predominantly undertaken using risk matrices. While other techniques and tools were mentioned as supporting risk assessment practice, some are not applicable to all steps of the risk assessment process. Furthermore, some of the ones that are applicable to all steps of the risk assessment process are claimed to be used infrequently, and if used, they can be used without training (Card et al. 2012b; Dul et al. 2012; Gray and Cohen 2012; Vincent et al. 2013; Ward et al. 2010).

Since current hospital risk assessment practice predominantly utilises risk matrices, the success of this practice is highly dependent on the use of risk matrices. However, the findings of this research reveal a number of issues with the guidance given on the use of risk matrices. Moreover, there are a number of inherent limitations identified in the literature regarding risk matrices (Ale et al. 2015; Ball & Watt 2013; Baybutt 2015; Card et al. 2013; Cox 2008; Cox & Popken 2007; Duijm 2015; Smith et al. 2009; Vatanpour et al. 2015). For instance, a risk matrix can only assess an individual risk at any one time (Cox 2008; Baybutt 2015), and quantitatively low risk ratings can be assigned to qualitatively high risk rating categories (e.g. high and moderate) (Cox 2008; Cox et al. 2005).

4.4.1 PROBLEMS WITH EXISTING GUIDANCE ON THE USE OF RISK MATRICES

The review of the risk assessment policies and procedures reveal a lack of clarity in the guidance provided in the following areas: the meaning of coloured bands, what to do when a risk could result in different consequences, which likelihood scoring scheme to use and in what circumstances, and the risk scoring strategy.

The bands on the risk matrices are designed to represent the tolerability of a risk (e.g. a green band refers to tolerable risks) (Macdonald 2004; BSI 2010). However, not all hospitals used this function of risk matrices. Hospitals instead used coloured bands to determine the level of a risk and the level of management action needed. In fact, considering the low reliability of risk scoring, the tolerability of a risk might require consideration of many other factors as part of the risk management strategy, in addition to likelihood and consequence. These factors include the detectability of a risk, the rapidity with which the risk will manifest itself and legal requirements (COSO 2012; Suddle 2009; ORR 2015). Yet, no mention was found in the collected documents to justify this as being a part of risk management strategy.

The majority of hospitals provided descriptions for scoring the consequence for different domains (e.g. for the impact on safety and reputation). However, no

guidance was found detailing what to do when a risk could result in different consequences for different domains. For instance, a potentially delayed cancer treatment might result in severe harm to patients as well as patient complaints and reputational damage at different scoring levels. This, however, can be considered as a limitation of the use of risk matrices. Risk matrices evaluate risks by considering a single consequence domain. To address this problem, aggregating or combining analysed risks has been recommended (BSI 2011b). Similarly, Card *et al.* (2013) suggested compiling an index of total assessed risk score. This allows risk assessors to consider all types of consequence domains as well as all potential consequences in the same consequence domain. However, there is no evidence found in the literature to support the effectiveness of such an approach.

Turning to guidance for scoring likelihood, hospitals provided different types of likelihood scales (i.e. nominal, time-framed and probability), and yet none of the hospitals provided any further guidance on when to use which type of likelihood scoring scale. Regarding suggestions to clarify which scales to use and when, it was stated, “*Probability scores have been developed for projects and business objectives*” (NPSA 2008). Similarly, Duijm (2015) recommends using probability for one-off projects and frequency for continuous operations.

It was also not always clear from the collected dataset what to do when a risk might result in different severity of consequences in the same consequence category. For instance, a risk of patient fall could result in different severities of harm such as no harm, minor cuts, or hip fractures. Some hospitals, however, provided a range of strategies for such circumstances. These strategies were namely adopting *the worst-case scenario*, *the highest risk score*, *the most likely scenario* or *the reasonably foreseeable worst-case scenario*. However, *the worst-case scenario* might lead to an over consideration of the most extreme cases; *the most likely scenario* might ignore the extreme cases; and *the highest risk score scenario* might require the measurement of risk scores for all possibilities, which could be considered to be time consuming. Although consideration of *the reasonably foreseeable worst case scenario* might also lead to the multiple

possibilities having to be worked out, this strategy is also recommended in the literature, where it is referred to as *the worst credible case scenario* (Pasquini et al. 2011; ORR 2015; AFSC 2000; Manuele 2014).

4.4.2 PROBLEMS WITH THE DESIGN OF CURRENTLY USED RISK MATRICES

Design-related problems primarily relate to the replacement of risk ratings by risk scores, and to the placement of the borders of the coloured bands.

		Consequence				
		1 Negligible No claim 0	2 Minor Claim <£10,000	3 Moderate Claim(s) £10,000- £100,000	4 Major Claim(s) £100,000- £1 million	5 Catastrophic Claim(s) > £1 million
Likelihood	5 Almost certain >50%	5 £0	10 £5,000- £10,000	15 £5,000- £100,000	20 £50,000- £1 million	25 >£500,000
	4 Likely 10%-50%	4 £0	8 £1,000- £5,000	12 £1,000- £50,000	16 £10,000- £500,000	20 >£100,000
	3 Possible 1%-10%	3 £0	6 £100- £1,000	9 £100- £10,000	12 £1,000- £100,000	15 >£10,000
	2 Unlikely 0.1%-1%	2 £0	4 £10- £100	6 £10- £1,000	8 £100- £10,000	10 >£1,000
	1 Rare 0-0.1%	1 £0	2 <£10	3 £0- £100	4 £0- £1,000	5 >£0

Figure 4.3 A quantitative risk matrix for M9

Hospitals replace risk ratings (a combination of consequence and likelihood values) by risk scores (multiplying consequence and likelihood scores, typically a score of between 1 and 25). At the same time, they use the real world descriptions for consequence (e.g. *minimal injury*, *minor injury*, *major injury leading to long-term incapacity and death*) and likelihood (*not expected to occur for years*, *annually*, *monthly*, *weekly* and *daily*) axes. However, the product of

consequence and likelihood scores will bear little relationship to the underlying risk ratings. For instance, a risk score of 25 is not 25 times as bad as a risk score of 1 from the description of the consequence and likelihood. To illustrate this concept, Figure 4.3 shows the significance of the risk ratings between the lower right and upper left corner as being £0 to over £500,000, instead of 1 to 25. Thus, the use of risk scores might mislead assessors in determining the significance of a risk, especially when comparing one risk to another.

While discussion here was about the replacement of risk ratings by risk scores, there are also limitations inherent to the use of qualitative risk rating categories (e.g. low, moderate and high). It has been claimed that the nominal descriptors (e.g. *negligible and minor; rare and unlikely*) are a simplification to make risk related decisions; identical qualitative risk ratings can be assigned to quantitatively different risk ratings; and quantitatively small risks could be assigned to a high qualitative risk rating categories (Cox 2008; Cox et al. 2005). Such limitations are demonstrated in Figure 4.3 by the use of the M9 risk matrix. The descriptions of the likelihood and consequence axes are used: *L:1 for $p < 0.1\%$, L:2 for $p = 0.1-1\%$, L:3 for $p = 1-10\%$, L:4 for $p = 10-50\%$, and L:5 for $p > 50\%$ for likelihood; and C:1 for no claim, C:2 for claim less than £10,000, C:3 for claim(s) between £10,000 and £100,000, C:4 for claims between £100,000 and £1 million and C:5 for claims more than £1 million for consequence (NPSA 2008).*

Figure 4.3 shows that a quantitative risk rating of £10,000 can be assigned to high or extreme risk rating categories. Furthermore, a risk score of 8, for instance, can be assigned to the quantitative risk rating of £1,000 to £5,000 (L:4 x C:2) as well as £100 to £10,000 (L:2 x C:4). These examples show that the use of risk scores as well as qualitative risk ratings categories can mislead assessors in determining the true value of the risks.

Some hospitals were found to use such asymmetrical risk matrices, where a risk score can be assigned to different risk rating categories when using the same risk matrix. Such matrices do not use the product of consequence and likelihood scores to establish risk rating categories. For example, a risk of incomplete orders of intraocular lenses might be something that hospitals could face at all times

(with a likelihood score of 5). However, they could manage this situation before it leads to any significant consequences (with a consequence score of 1). On the other hand, a risk of failure to the manual handling of infectious blood samples might be something which is not expected (with a likelihood score of 1), yet it could lead to multiple organ failure and death (with a consequence score of 5). While both risks are scored as 5 ($L:5 \times C:1$ and $L:1 \times C:5$), the latter situation is something far less desirable than the former. However, the use of risk scores assigns them to the same risk level; whereas the use of M22, which is an asymmetrical risk matrix, would assign the former as a low risk and the latter as a high risk. While technically this could be considered as an inconsistency in the use of risk matrices, practically it can be explained as a result of organisational strategy. These hospitals may have designed the coloured bands on the risk matrices by determining risk ratings rather instead of risk scores. However, no rationale has been found to explain why these hospitals use asymmetrical risk matrices.

Additionally, results show that two risk matrices (M3 and M6, see Figure 4.2) share an edge between green and red cells even if there is an intermediate band between green and red cells. Cox (2008) criticises this matrix design since it could lead to categorising risks incorrectly and recommends adding an intermediate band between green and red cells. Indeed, all hospitals that reviewed in this study use risk matrices with at least one intermediate band. However, Cox (2008) also warned that having two or more intermediate bands could also lead to incorrectly categorising the risk ratings, and 77 percent of the hospitals have two or more intermediate bands. The limitations inherent in risk matrix designs, therefore, increase the risk of misprioritisation.

4.4.3 FURTHER CONSIDERATIONS REGARDING THE USE OF RISK MATRICES

There are some limitations inherent to the use of risk matrices which also apply to the risk matrices currently used in hospitals.

The risk rating is assigned to the risk matrix by simply determining the likelihood and consequence of the risk. However, this simplification has recently been criticised by some researchers and it is recommended that additional factors are considered (Aven 2017; Khorsandi and Aven 2017; Askeland et al. 2017). These factors include determination of the uncertainty about the events and their consequences, and the strength of knowledge of the assessors (Aven 2011; Aven 2012b; Aven and Krohn 2014). On one hand, these factors may indeed help better estimate the real value of risks. The strength of knowledge of assessors can be evaluated by considering data used for the assessment, the justification for the assumptions made, and by reaching agreement between the assessors regarding the assessment (Aven 2017). On the other hand, it adds more complexity to the current practice, which may be undesirable in hospitals under current circumstances.

A risk matrix can only assess an individual risk at any one time (Cox 2008; Baybutt 2015), which limits the understanding of the links between different risks. Many of the risks immediately evident are linked to other less visible risks: for instance, a risk to inpatient bed capacity may be linked to delays in surgery, and delays in discharge. However, other tools and techniques can be also used with risk matrices to address this challenge. For instance, FMEA may help to identify all undesired events in relation to the system to be assessed, and the bow-tie technique may help in understanding the pathways of a risk from its sources to consequences (BSI 2010). However, FMEA still works on a single failure assumption. Furthermore, there is little evidence to show that such tools, especially the bow-tie, are used in healthcare (Broggi et al. 2013; Chatzimichailidou et al. 2017; Lago et al. 2012; Wierenga et al. 2009) and thus understanding of risk relationships may remain poor.

Subjectivity also impacts the effectiveness of risk matrices. While a qualitative risk rating system itself involves some subjectivity (Cox 2008), cognitive bias leads to subjectivity in judgements as a result of different perspectives stemming from job function or seniority, personal experiences and the level of confidence (Ball and Watt 2013; Hubbard and Evans 2010; HSE 2001; Smith et al. 2009).

Furthermore, individuals might purposefully be subjective. Risks can also be deliberately understated or overstated in order to avoid or gain management attention. For instance, a study revealed that the patient risk of metal phosphide poisoning was overstated due to the ethical and legal issues involved (Nocera et al. 2000). Suggestions to overcome these problems include the use of quantitative data, risk scoring guidance and a separate risk matrix for each consequence domain (e.g. financial and harm related consequences), as well as through the involvement of team assessment, and peer review (Card et al. 2013; Duijm 2015; Aven 2012a). Since data in healthcare might not be easily quantified, providing better guidance on scoring risks and encouraging staff to use this guidance may be helpful to overcome bias in decisions. However, anecdotal evidence so far shows that healthcare staff might score risks without consideration of the descriptors behind the scores. As a result, different individuals might score the same risk differently even in the same hospital.

In summary, there are a number of limitations to using risk matrices explored in this section that might lead to errors in risk prioritisation and inadequate resource allocation. However, there are also real advantages to using the risk matrices as a tool in assessing risks. A risk matrix helps to visualise risks through using coloured cells, and there is no need for expertise to use this tool (Cox 2008; Thomas et al. 2014). These features make the risk matrices the most commonly used tool to assess risks in hospitals.

In order to obtain greater benefit from the use of risk matrices, the gaps in current practice need to be addressed, although it must be noted that simplicity is a key attraction of risk matrices particularly in a hospital context. Bearing this in mind, the following pages provide suggestions for potential improvements to the currently-used risk matrices in hospitals.

Due to the limitations of risk scoring and risk matrices, one recommendation might be to replace the risk scoring mechanism with a risk rating mechanism and to use a risk matrix with three coloured bands. However, the use of a qualitative risk rating mechanism would require more time to prioritise risks since all risk ratings are assigned to three categories (e.g. low, moderate and high). There are

also limitations inherent to qualitative risk rating, as mentioned earlier. While the use of a quantitative risk rating mechanism may overcome some of the limitations of qualitative risk rating, quantification may limit the main attraction of risk matrices. For example, quantification of data in healthcare might not be easy and it might be unreliable in some cases. Therefore, it is essential to be aware of the limitations inherent to the risk matrices used, and not to solely rely on risk scores when making risk-based decisions.

Building on the all discussions so far, further recommendations on use of risk matrices in English acute hospitals can be summarised as follows:

- Clarify the terminology used in risk assessment.
- Introduce guidance on what to do when a risk has several consequences in multiple domains (e.g. a single risk may lead to personal injury, economic loss or reputational damage).
- Clarify which likelihood scoring scheme (i.e. nominal, time-framed and probability) to use in which circumstances.
- Clarify how risk should be scored where a range of consequence could occur with different likelihoods (e.g. a risk of patient fall could lead to no harm, minor cuts or hip fracture with different likelihoods).
- Remind risk assessors that risk scores might show little relation to the real risk rating, and, therefore, a balanced and unbiased professional judgement should be involved when making risk-based decisions.
- Remind risk assessors that a risk matrix is not a tool for them to make decisions; but rather is one of several methods designed to support their decisions.

Indeed, hospitals may assess risks by considering multiple other factors. These other factors may include a consideration of the cost of recommended actions, the ease of these actions, their implementation time, the urgency of mitigating the risk, and social and organisational factors (Baybutt 2015; Haimes 2012; Ruzante et al. 2010; Smith et al. 2010; Choo et al. 2010). Thus, the risk

assessment may involve professional judgement to determine all these factors in conjunction with the use of risk matrices.

While a number of recommendations have been made regarding current recommended risk assessment practice, the limitations of this analysis should also be mentioned. The main limitation of this study is that the reviewed risk management policies and procedures may not reflect the actual practice of risk assessment. In practice, these documents may seldom be referred to, and could in turn be considered only as a paperwork exercise rather than fulfilling their purpose of providing good guidance on risk assessment. However, this study aimed to reveal '*work as described*', while the next chapter investigates '*work as done*' to reveal actual practice.

4.5 SUMMARY

This chapter examined the recommended risk assessment practice in acute hospitals in NHS England through the analysis of risk assessment policies and procedures. The findings of this chapter revealed that risk matrices play a key role on organisation-wide risk assessment practice, and different hospitals might use different types of risk matrices by providing a different level of guidance. However, the main concerns identified here are the adequacy of the guidance provided and the limitations inherent to the risk matrices. Risk matrices may be being used inappropriately by hospitals, who may then inadvertently reach inadequate decisions and inadequately deploy resources to manage risks. While there is not a magical solution to improve the current design and the use of risk matrices, hospitals can improve their current recommended risk assessment practices by providing better guidance on risk scoring and risk terminology as well as by encouraging their staff to identify and understand the limitations inherent to risk matrices.

The following chapter presents evidence regarding actual risk assessment practice as currently conducted in hospitals in NHS England.

CHAPTER 5

ACTUAL RISK ASSESSMENT PRACTICE IN HOSPITALS IN NHS ENGLAND

5.1 INTRODUCTION TO ACTUAL PRACTICE

This chapter explores the actual risk assessment practices, '*work as done*', in hospitals in NHS England. A set of exploratory studies was conducted to gain an understanding of overall risk assessment practice, to reveal the practical experience of NHS staff of risk assessment practice, and to highlight the challenges within current risk assessment practice. This was undertaken through conducting interviews and questionnaires, investigating a risk register database, and reviewing the Board Assurance Framework (BAF) documents.

At the end of this chapter, the overall risk assessment practice is explained, and a number of requirements are identified for the design of a proposed risk assessment approach in hospitals.

5.2 OBSERVATIONS FROM INTERVIEWS

5.2.1 METHODS

Informal and formal interviews took place in order to reveal the practical experience of NHS staff of risk assessment in hospitals. A purposive sampling technique was used to ensure participants had sufficient experience of risk assessment, and to involve existing contacts of the research group at the Engineering Design Centre in this study. The inclusion criterion for both the informal and formal interviews was to select participants who have been involved in at least one risk assessment.

Informal unstructured interviews took place with five NHS staff from a single acute teaching Trust, to extend the researcher's understanding of the current risk assessment practice as well as to understand participants' experience in risk assessment. Interviews were arranged by sending invitation emails to existing contacts working at the single acute care teaching Trust. The interview date and time were arranged according to the availability of each participant. Following that face-to face interviews were conducted, and written notes were taken during the interviews. All data from the interviews were recorded on the researcher's office computer after removing all personal information (if there was any) and a unique code was added for each participant.

Formal semi-structured interviews took place with twelve NHS staff from multiple Trusts to understand participants' experiences in risk assessment. Questions for the formal interviews were developed by the researcher based on the literature findings with some input from the research team (see Appendix 5 for the interview schedule). Interviews were arranged through sending invitation emails to potential participants. In addition to the use of existing contacts, the researcher identified potential participants through reviewing profiles of NHS staff on LinkedIn. The selection of these participants was based on their profile information to ensure they have sufficient experience of risk assessment. After filtering their profiles based on their job titles, a number of participants were

selected and sent the invitation email. The information sheet (see Appendix 6) and interview schedule (see Appendix 5) were also attached in the email. Telephone interviews were preferred to allow healthcare staff from different geographical regions to participate without the barrier of travel. However, there was a bias towards participants from the East of England for practical reasons so as to allow face-to-face interviews, where possible, in addition to telephone interviews.

After receiving approval from participants in the formal interviews, the interview time was arranged and a consent form (see Appendix 7) was sent via email. Informed consent was obtained either verbally prior to the interview or as a signed form. At the beginning of the formal interview, participants were informed about the research study. Then, interviews were audio recorded with the permission of the participants. After the transcription of the audio recordings, a unique code was added for each participant. All data were then analysed anonymously.

Collected data from the formal interviews were analysed to identify key themes in participants' understanding of risk assessment. To do so, inductive thematic analysis was used. Transcripts were read, and coded by the researcher. The coding processes were manually conducted by reading the printed transcripts. First-cycle coding was conducted to list all codes. Second-cycle coding focused on the relationships between different categories to identify key themes. To reduce bias, discussions were made with three researchers on the emerging themes. After that, codes were clustered under five different themes:

- Description of risk assessment
- Experience of conducting a risk assessment
- Experience with the use of an organisational risk matrix
- Experience with the use of risk assessment guidelines
- Difficulties of conducting risk assessments.

5.2.2 RESULTS FROM INFORMAL INTERVIEWS

Since the informal interviews were unstructured and not audio recorded, results only present the key observations based on the notes taken. Five informal unstructured interviews were conducted with healthcare staff from a single acute teaching hospital. Characteristics of these participants are given in Table 5.1.

Table 5.1 Characteristics of the participants for informal interview

Identifier	Interview Type	Position
F1	Face-to-face	Health and Safety Officer
F2	Face-to-face	Head of Patient Safety
F3	Face-to-face	Assistant Director-Risk and Patient Safety
F4	Face-to-face	Datix System Manager
F5	Face-to-face	Risk and Quality Advisor

Informal unstructured interviews were held between 2014 and 2015. The researcher arranged meetings for an hour and the duration of each interview was approximately 45 minutes. Interviews were conducted primarily to extend the researcher's understanding of the current risk assessment practice and to understand participants' experiences of current risk assessment practice. Thus, the researcher started the conversations by asking general questions such as *"How is risk assessment conducted?"*, *"Which tools are used to conduct risk assessments?"*, *"Who conducts risk assessments?"*, and *"How does the risk register system work?"*. Although there were some other topics that were discussed with participants such as in incident reporting systems, patient discharge problems, and health and safety manuals, these parts were not mentioned in this section since they were found to be less relevant to this research study.

It was observed that a health and safety officer (F1) had a slightly different view than other participants. He was confident about the assessment of health and safety related risks in the hospital. F1 also claimed that their practice meets with the Management of Health and Safety at Work Regulations 1999. Others, however, predominantly focused on the negative sides of the current risk

assessment practices in the hospital. This could be due to the fact that health and safety risk assessments tend to be conducted by the health and safety staff, whereas other types of risks tend to be assessed by clinical staff, who have less experience of risk assessment.

Participants gave two ways in which risk assessments were conducted, either by completing a risk assessment form or registering a risk through the use of Trust's risk register system. The risk register system is a database that can be easily accessed through Trust's intranet page, and it contains multiple steps that require the involvement of multiple staff from different levels. Front line staff register risks, and risk leads approve these entries as well as making adjustments to them if necessary. Following that, the assigned level of staff decides whether or not to take any action, with the decision based on the level of risks. If the assigned level of staff cannot resolve these risks, these risks are escalated to a more senior level.

F2 explained that a risk matrix with 3 coloured bands is embedded in the risk register system to prioritise risks. Risk owners score likelihood and consequence of the risk from 1 to 5, and then assign the risk scores (1 to 25) to the Trusts' risk matrix. A higher risk score gets a higher priority in terms of the management of the risk. A risk score of 15 or above is deemed a high risk; a risk score of between 8 and 15 a moderate risk; and below 8 a low risk. However, F4 stated that risks are over scored in order to attract managerial-level attention to solve an existing problem. F2 and F3 pointed out the subjectivity of risk scoring on the risk register system. Similarly, F5 stated that *"different people have scored the same thing in very different ways"*. This could be a result of healthcare staff scoring risks using their professional judgement rather than basing them on the explanations behind each likelihood and consequence score.

Although the risk register system is in place in the Trust, participants highlighted a number of problems with its use. For instance, F2 said *"People tend to use the risk register system to get money or to cover their back by claiming that they warned the managerial level through registering risks."* F1 claimed that the approval process can take too long and suggested that it requires a time limit (e.g. 72

hours), after which the entry, should be removed from the approval page. Indeed, F5 stated that there are a lot of risk assessments awaiting approval in some divisions, which discourages people from undertaking future risk assessments. In addition, F5 also pointed out that while the risks are registered, often no subsequent action is taken.

When participants were asked *“Who should be involved in a risk assessment practice?”* they all gave the same response, claiming that everybody should be involved. However, they all admitted that this does not happen in practice, and it is often only a few staff who are involved in risk assessments. Yet, it was also observed that participants were keen to improve their current risk assessment practice. For instance, F4 was working on a project to upgrade the Trust’s risk management system, and F5 and F3 were keen to use prospective hazard analysis techniques. However, F5 highlighted that very few people have training on such techniques, except RCA techniques are a commonly used in the Trust. F1, who delivers risk assessment courses, also claimed that the Trust needs more training for all staff.

Although these results only reflect the participants’ views in risk assessment or the researcher’s observations from these unstructured interviews, F3 stated that his experience with other Trusts’ risk assessment practices was similar to that of his current Trust. He also added that some Trusts might be better in some areas, such as in the assessment of strategic risks, and others are better in other aspects such as operational risk assessments.

5.2.3 RESULTS FROM FORMAL INTERVIEWS

Twelve formal semi-structured interviews were conducted with healthcare staff from seven different Trusts and two other organisations (NHS England and a consultancy company). Eleven interviewees gave permission to audio record the interview. One interviewee preferred not to be recorded, but allowed the researcher to take some notes during the interview. The average length of time

spent in an each interview was 46 minutes. The characteristics of the participants for the formal interviews are provided in Table 5.2.

Table 5.2 Characteristics of participants for formal interviews

Identifier	Interview Type	Interview Duration	Type of Trust	Job Title	Years of Experience in NHS	Safety and Risk Management Training
T1	Telephone	46 mins	Acute	Head of integrated clinical governance	38	Risk assessment, risk management, FMEA and RCA
T2	Telephone	26 mins	Mental health	Team leader	27	Risk assessment and suicide prevention
F6	Face-to-face	48 mins	Acute teaching	An anaesthetist	9	Simulator training
T3	Telephone	49 mins	Other	Head of patient safety investigation	33	Risk management
T4	Telephone	34 mins	Acute	Clinical engineer	7	Managing safely, RCA and risk management
T5	Telephone	53 mins	Acute	Clinical engineer	10	Risk assessment
T6	Telephone	36 mins	Mental health	Team leader	15	Risk assessment and risk management
T7	Telephone	45 mins	Mental health	Patient safety practitioner	15	Risk assessment
T8	Telephone	60 mins	Other	Risk management consultant	10	Health and safety risk assessment
T9	Telephone	42 mins	Acute teaching	Quality improvement fellow	16	Risk management
F7	Face-to-face	69 mins	Acute Specialist	Head of nursing	30	Risk assessment, RCA and risk management
T10	Telephone	50 mins	Acute Specialist	Risk manager	30	Health and safety, risk management, RCA, IOSH, risk officer and human factors

Table 5.2 shows that participants were involved from a range of Trusts, including acute, acute teaching, mental health and acute specialist. The average number of years of experience per participant was 20 years. All participants had received at least a single safety-training programme.

5.2.3.1 Description of risk assessment

Four participants claimed that risk assessment is something they do unconsciously at all times. For instance, T2 described the risk assessment as *“your sub-conscious”*. F6 explained it as *“learnt behaviour”* and highlighted that everyone does it differently. Likewise, T4 expressed it as *“judgement of the consequences of the incident”* and T7 as *“having a good conversation with an individual to find out what is going on”*. T8 and F7 highlighted that risk assessment is used to prevent patient harm. However, some other participants provided a wider perspective for the aim of risk assessment by defining it as *“looking for unforeseen events, which may be positive or negative, and then planning and mitigating these events”* (T9) or *“It covers all variety of risks within the hospital including strategic, financial, health and safety and clinical”* (T10). T5 also described risk assessment as a process of risk identification, risk analysis and the consideration of control measures to manage that risk.

Turning to the recommended risk assessment practice, risk assessment was often defined as a systematic process of assessing the likelihood of something happening and its potential consequence. However, participants provided a variety of descriptions for risk assessment, and participants’ roles were found to have an impact on their responses. Arfanis *et al.* also highlighted that people from different professions with varied degrees of training and experience possess different levels of understanding of risk (Arfanis et al. 2011). For instance, on the one hand, all participants working in Mental Health Trusts provided a definition that refers to something they do as part of their daily jobs. This could be due to the fact that every individual referred to the mental health services should receive a risk screening, which involves an overall assessment of the broad areas of potential risks (DoH 2010). On the other hand, participants working in acute hospitals tend to be involved in risk assessment less frequently and often follow a more systematic risk assessment process.

5.2.3.2 Experience of conducting a risk assessment

Six participants shared experience in risk assessment with the use of a risk assessment template or form; four with a risk register system; three with RCA, two with FMEA; two with a safety walkabout; one with a checklist; and one with professional judgement. Clearly, some of the participants mentioned their multiple experiences, and the use of these techniques reveal that participants use the techniques and tools that are recommended in their organisational risk assessment policies and procedures.

All participants defined their risk assessment experience as a team assessment, or at least involving different individuals at different stages of the assessment.

Three participants described risk assessment experiences based on the risk assessment of individual patients. For instance, T2 described her experience with a patient coming into accident and emergency who had overdosed with alcohol and needed medical treatment. Since the reason behind taking the alcohol overdose was not resolved, her team considered that the patient was at risk of taking an overdose again. The team assessed the risk through the use of their personal judgement. T7 depicted her experience with assessing the risk of self-harm of a patient while moving her from young patient insecure services to adult insecure services through the use of a risk assessment form.

Five participants stated that their risk assessment experiences came from investigating incidents such as patient fall risk assessment (T9) and medical device-related incident investigation (T5). Two participants described their experiences with health and safety risk assessment, namely the risk assessment of trip hazards (T8) and new hospital designs (T10). In addition, two participants (T9 and T10) described their role in assessing project risks and strategic risks, and three participants (T1, F7 and T10) recounted their role in reviewing risks.

Overall, the findings show that three ways of assessing risks are used: individual patient-based risk assessment through the use of professional judgement, operational risk assessments through completing a risk assessment form, and

specialised risk assessments through using specific risk assessment forms (e.g. suicide and patient falls). In turn, risks are either qualitatively assessed often through the use of professional judgement, or semi-quantitatively assessed through the use of risk scores.

5.2.3.3 Experience with the use of organisational risk matrices

Since the risk matrix is embedded in the risk register system and organisational risk assessment forms, the researcher asked further questions regarding their experience with risk matrices. Ten out of twelve participants provided their opinions on risk matrices used in their Trusts. For instance, T2 found risk matrices helpful for supporting conversations about risk, F5 viewed it as a supporting mechanism to professional judgement, and T4 found it provided a common language. Likewise, T3 claimed, *“I think people know risk matrices well”*. Furthermore, T3 commented that *“I quite like [risk matrices], because they make people argue less about the numbers”*, and T10 found them helpful, saying *“The risk matrix helps us in a variety of ways: to prioritise risk, to make sure we are raising awareness, and to give people the understanding of what needs to go to what level of committee and responsibility”*.

However, participants also criticised the risk matrices in terms of the subjectivity of the risk scoring (T9) and the danger of risk matrices being another tick-box exercise (T8). While subjectivity of the risk scoring can be minimised by the use of guidance, all participants admitted that they often do not use risk-scoring guidance when they assess risks. However, they claimed that they would talk to their colleagues when they are unsure about the score of a risk.

Additionally, risk matrices were criticised regarding their use in risk prioritisation. It was recommended other factors should be considered when prioritising risks (T2, T3 and T4). For instance, T3 suggested consideration of *“public opinion”* or *“the easiness of the implementation of the recommended actions”*. Yet, risk matrices were highly appreciated and no alternatives were suggested to replace them.

The findings overlap with the findings from the previous chapter as well as the literature review. The simplicity of risk matrices is their main attraction, and the problem with subjective risk scoring is recognised by healthcare staff. Nonetheless, none of the participants mentioned the limitations inherent to risk matrices.

5.2.3.4 Experience with the use of risk assessment guidelines

To guide their assessment of risk, four participants use their Trust's risk assessment policies (e.g. organisational risk assessment policies and clinical risk assessment procedures). Two other participants stated that they usually follow the NPSA guidance, *A risk matrix for risk managers* (NPSA 2008) and two others follow Health and Safety Executive (HSE) guidance, *Five steps to risk assessment* (HSE 2006a). The remaining four participants stated that they do not really follow any guidance when assessing risks, however they know where to find it.

Most of the participants explained that healthcare staff often do not read guidance. For instance, T4 claimed, *"I do not think anyone would go through these documents"* and F7 claimed that *"Nobody is reading the guidelines"*. Furthermore, T9 admitted that *"I am sure there are guidelines, but I do not know them"*, and F7 pointed out that clinical staff would read policies if they feel a need for any support to conduct risk assessments.

Since the reviews of the risk assessment policies in Chapter 4 reveal that they are not in most cases adequate to guide healthcare staff in assessing risk, this perhaps could be one reason for the participants' lack of interest in such policies to do so. However, when participants were asked their opinion on designing a new risk assessment framework to guide them, they responded more positively and recommended a number of points for its design. Participants advised that the developed framework should fit with their existing risk assessment practice. T3 pointed out that having a framework that explains all key points of risk assessment to be applicable to all types of risks would be useful; T7 stated that frameworks would make people think to conduct more effective risk

assessments; and T6 thought that *“It would help, if somebody sits down and designs something like that”*. However, T1 advised that *“It has to be simple, easy, and accessible”* and T8 warned, *“If it doesn’t fit one size of A4, it is too complicated. You have to start incredibly simple”*.

The findings indicate that while there is a recommended practice, actual practice does not always follow this.

5.2.3.5 Difficulties in conducting risk assessments

The participants outlined a number of challenges which fall into ten categories as follows: (1) the application of risk assessment, (2) terminology, (3) training, (4) risk communication, (5) risk assessment tools, (6) risk scoring, (7) risk prioritisation, (8) time requirement, (9) fear of punitive measures and (10) post-assessment actions.

F6 claimed that risk assessment is most likely to be conducted following an incident. T7 admitted that they identify risks, but wait for something to happen to take action regarding those risks. T3 stated, *“People do not understand the science behind it [risk assessment], and they make poor decisions”*. Additionally, T1 and T8 claimed that the root causes of the assessed problems are often not identified. T8 and T10 mentioned the lack of attention given to near misses. In relation to this, T10 asserted that a very important near miss could have led to death if it had gone differently. While participants highlighted a number of challenges, they also provided some recommendations for potential improvements. For instance, they ascertained that the application of current risk assessment practice could be improved by providing training (T3), defining risks related to their objectives (T1), encouraging staff to conduct risk assessment before harm occurs (T8), understanding the problem (T9) and looking for good motivators (T10).

The majority of the participants, whatever their profession, highlighted issues regarding risk terminology, except participants from Mental Health Trusts. T3 claimed that people often do not know what the definition of risk means; F7 said,

"I think the language [risk terminology] is a problem" and, similarly, T10 said *"They still struggle with the terminology and writing things out."* Conversely, T5 claimed that the terminology was clear for him and his team, and T8 said that *"I think our team knows about risk assessment, we try not to use the terminology in our team"*. To address terminology related issues, participants recommended the use of ordinary language. For instance, T3 suggested, *"It might be worth using plain English"*. She then provided an example saying that it is useful to use 'how big and how often' instead of 'risk analysis'.

In addition to this, participants mentioned the problem of training staff in risk assessment. T2 suggested *"I think there needs to be far more training on doing a good risk assessment"* and similarly, T10 agreed but added, *"We struggle to get people to training, purely because of staffing levels"*. T3 also highlighted one of the consequences of staff not being trained on risk assessment, claiming *"If people are not trained in risk assessment, they use the risk matrix badly"*. To provide better training, F6 commented, *"If we were trained to be a bit more systematic in how we thought, we could explain things better. Risk assessment would be much better"*. T3 recommended, *"I think they do not see enough real life examples. All they see is the risk register or risk matrix."* Yet, T8 acknowledged *"I worked in organisations that changed their culture by training enough people."*

Participants also mentioned risk communication as a challenge of their risk assessment practices. T5 said that *"The major barrier is the communication and then seeing the output together as a team from start to end."* and F6 declared that it is difficult to have conversations about risks and actions required to minimise those risks. On providing better communication, T2 recommended that *"having frank discussion about the risk and not being scared to ask difficult questions are the factors leading to good risk assessment."*

Additionally, T3 claimed that there are only a few tools to assess risks. Yet, T7 commented that people are seeking more tools to assess risks and they are more willing to learn them.

Risk scoring was another issue that participants raised. Participants criticised the subjectivity of risk scoring and the low reliability of risk prioritisation since it is based on risk score. For instance, T1 stated, *"They all score it differently"*. Similarly T5 claimed *"Somebody might rate it as a very high risk, but it might not be a very high risk"* and T3 said *"If you do not have the right people in the room, you can really get it wrong."* To overcome the problems with risk scoring, F7 asserted, *"I would probably change things down, more than change things up. Because I would just think in a bigger picture than perhaps someone who is annoyed with that thing at the time"*. This requires authority to enact.

Turning to the problems with risk prioritisation, T8 highlighted the need for considering detectability in addition to likelihood and consequence. T8 said, *"They are using severity and likelihood, but they are not using the third factor, which is likelihood of [the failure] being discovered."*

T7 and T9 identified that undertaking the risk assessment process itself is a challenge, since it requires time and their available time is limited. T9 said, *"In nursing, when you have to do a risk assessment [complete a risk assessment form], it is like a six-page document and it takes you forever. And it is not an enjoyable process."* These participants mentioned their desire to have shorter forms to make the assessment of organisation-wide risks (e.g. clinical and non-clinical) a quicker process.

Another issue raised was punishment of the organisation after harm occurs, with F7 sharing her concern that *"There is a bit of carrot and stick involved. Obviously, we do not want any harm to come to our patients, but if we are not doing the right thing, we will be punished as an organisation as a result of that"*. Consequently, Trusts may focus on assessing risks to meet regulatory requirements in order not to be punished rather than focusing on risk reduction.

In addition to these challenges, further difficulties were identified after the application of risk assessment. T1 mentioned a problem with post-assessment practice by saying *"Again, a big gap in the NHS organisations is the action plan. So, action plans just disappear. You do your risk assessment, this is what we are*

going to do about it and no one ever goes back and looks at it.” Other participants also agreed with this by stating that problems are defined, but then nothing is done about them. T3 also highlighted this, saying *“Risk assessment should result in a statement, which results in an action. And that is the bit that never ever happens”*.

The healthcare literature has already identified some of these challenges such as insufficient guidance and biased risk scoring. These interviews with healthcare staff indicate that the problems are ongoing. In fact, most of these challenges concern the clarification of the foundations of risk assessment practice and its application, including how to express risk and how to conduct risk assessment (Eidesen et al. 2009). While some of the challenges have also been experienced in other industries, such as ambiguity in risk terminology (Aven 2010; Aven and Zio 2011; Aven and Renn 2009), safety-critical industries have reached a more mature safety level and can provide a role model for healthcare to follow (Sujan et al. 2015; Vincent et al. 2014).

In summary, the findings from interviews reveal that different individuals may have different views on risk assessment; that a range of techniques can be used to support risk assessment by following different risk assessment approaches; that *‘work as described’* in relation to risk assessment can be different from *‘work as done’*; that participants appreciate risk matrices but also recognise the basic problems in relation to their use; and that some of the challenges of conducting risk assessments have not been addressed yet.

However, the limitations of the study should also be noted. Firstly, the results of this study only reflect the views of participants due to the purposive sampling. It is possible that different individuals might conduct risk assessments differently. For instance, participants working in Mental Health Trusts focus on the individual patient-based risk assessments either assessing risks by using their professional judgement or completing a specific risk assessment forms as in self-harm. Clinical engineers focus on medical device risk assessments through the use of risk assessment forms. Secondly, the relatively low number of participants, and having participants from different trusts, can be considered a limitation of this

study. Thirdly, the analysis of the interview data may also contain limitations. In this study, no further validation was conducted to ensure the reliability of analysis other than conducting group discussions with the research team. For instance, a second-cycle of interviews could have been conducted to ensure that all necessary data were collected from every single interviewer, and key themes and interpretations of the researcher were confirmed by participants. To mitigate such limitations, further evidence was collected in the next section.

5.3 EVIDENCE FROM A QUESTIONNAIRE

5.3.1 METHODS

A questionnaire was administered to reach additional participants and thereby to obtain more evidence of the practical experience of NHS staff. A purposive sampling strategy was used to select participants with an understanding of risk assessment.

There were sixteen questions in the questionnaire (see Appendix 8). The questions were designed to understand the characteristics of the respondents (e.g. their position and organisation type), to reveal respondents' opinions on current practice and to interpret their knowledge of the topic. There were two open-ended and fourteen closed-ended questions. For each closed-ended question, participants were allowed to write their opinion through an 'other' option. The research team tested the prepared questionnaire in terms of the clarity of questions and time requirement. Both electronic and paper-based versions were prepared. The paper-based questionnaire was distributed and completed by participants during a healthcare safety event. The electronic questionnaire was designed through the use of Qualtrics survey software. It was disseminated through posting a questionnaire link to relevant groups on LinkedIn. Additionally, invitation emails were sent to the existing contacts. Informed consent was obtained through a paragraph at the front of the questionnaire. After conducting the questionnaire, all data were recorded on the researcher's

office computer. The Statistical Package for the Social Sciences (SPSS) V.24.0 was used to analyse questionnaire data in order to reveal evidence of a relationship between any two questions, such as between respondents' profession and the respondents' view on the sufficiency of existing guidance. To this end, the responses of nominal and ordinal variables were stored as numerical values (e.g. 1 to 5 for Likert Scales) and Chi-square tests were conducted.

5.3.2 RESULTS FROM THE QUESTIONNAIRE

69 responses were received from the questionnaire: 30 paper-based and 39 electronic. Responses that did not meet the inclusion criteria (n=8) were excluded from the study. Table 5.3 lists the characteristics of the 61 respondents.

Table 5.3 Characteristics of questionnaire respondents

Characteristics	Number (%)
Profession	
Clinical	41 (67)
Non-clinical	20 (33)
Trust type	
Acute	30 (49.2)
Acute specialist	8 (13.1)
Mental health	22 (36.1)
Ambulance	1 (1.6)
Risk training	
Received	55 (90.2)
Not received	6 (9.8)

The majority of the respondents (n=41) were clinical staff (e.g. nurses, doctors and psychiatrists), working in acute or Mental Health Trusts. Non-clinical respondents (n=20) (e.g. risk managers, heads of quality governance and clinical engineers) were managerial staff or staff having no direct contact with patients. Almost all non-clinical staff (n=19) had received at least one session of safety or risk management training (e.g. health and safety, risk assessment and root cause analysis). Similarly, a large number of clinical staff (n=36) had received training.

There were 6 respondents who did not receive any training but who are still involved in risk assessment in their working Trusts.

The majority of the participants were involved in risk assessment. The respondents' frequency of involvement in a risk assessment is presented in Figure 5.1.

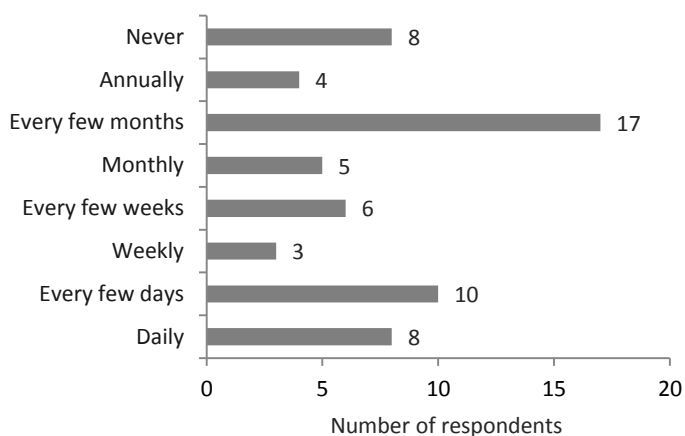


Figure 5.1 Respondents' frequency of involvement in a risk assessment

Respondents were asked "*What is risk assessment used for?*" and they were allowed to select multiple options from a range of potential answers. The potential answers were based on the literature review findings as well as the findings from the previous studies in this thesis, and the responses are summarised in Table 5.4.

Table 5.4 Responses for the aim of risk assessment

What is risk assessment used for?	Number of responses (%)
Assessing potential harm	56 (91.8%)
Registering risk	48 (78.7%)
Meeting responsibilities	40 (65.6%)
Investigation of incidents	30 (49.2%)
Highlighting actions taken	24 (39.3%)
Assessing who to blame	9 (14.7%)
Other	10 (16.4%)

Note that ten participants selected the option of other in Table 5.4. While some of these participants gave a response similar to the provided options, such as *“reduction of harm”*, other responses included *“support service, design, manufacture and maintenance of medical devices”*, *“taking preventative actions”*, *“professional performance”* and *“maximising the well-being of service users”*.

Participants were then asked which tools and techniques they use to assess risks, presented in Table 5.5.

Table 5.5 Responses for the techniques and methods used to assess risks

Which methods and techniques do you use to assess risks?	Number of responses (%)
Root cause analysis	42 (68.9%)
Risk matrix	24 (39.3%)
Software/ system	16 (26.2%)
Failure mode and effect analysis	11 (18%)
Fault tree analysis	9 (14.7%)
Event tree analysis	9 (14.7%)
What-If (SWIFT)	8 (13.1%)
Barrier analysis	8 (13.1%)
Human reliability analysis	7 (11.5%)
Hazard and operability analysis	6 (9.8%)
Other	13 (21.3%)

Additionally, participants were asked how likely they were to find risk assessment easy to carry out and how likely they were to conduct a risk assessment following an incident. Table 5.6 shows the results.

Table 5.6 Respondents' view on given statements

Statements	Not likely at all	Not very likely	Somewhat likely	Very likely	Extremely likely
Risk assessment is easy to carry out	2 (3.3%)	19 (31.1%)	15 (24.6%)	20 (32.8%)	5 (8.2%)
Respondent conducts a risk assessment following an incident	2 (3.3)	7 (11.5)	14 (22.9%)	30 (49.2%)	8 (13.1%)

More than half of the respondents found risk assessment easy to carry out. The majority claimed that they would conduct a risk assessment following an incident.

When the respondents were asked about current difficulties in conducting risk assessment, they selected at least one of the given difficulties outlined in Table 5.7. Additionally, almost 15 percent of respondents identified additional difficulties, which are either very similar to one listed in Table 5.7, or new, such as *“limited resources”*, *“lack of evidence”* and *“lack of shared knowledge”*.

Table 5.7 Responses for the difficulties of risk assessment

What are the current difficulties to conduct a risk assessment?	Number of responses (%)
Limited time availability	35 (57.4%)
Perceived value of risk assessment	32 (52.5%)
Insufficient knowledge/skills required	25 (41%)
Lack of guidance	18 (29.5%)
Lack of support from above	13 (21.3%)
Others	9 (14.7%)

When participants were asked, *“Who should be involved in a risk assessment?”* the vast majority (n=53) selected the option of *“all staff”*. Their responses reflect the Trust’s policies and procedures since risk assessment is a corporate responsibility. In addition, some respondents added *“contractors and manufacturers”* and *“carers and relatives”*. This indicates that subject matter stakeholders play important roles in risk assessment practice.

Table 5.8 Responses for the optimum time needed to complete a risk assessment

How long should each risk assessment take to complete?	Number of responses (%)
Depends	24 (39.3%)
Up to 30 min	16 (26.2%)
30 min- 1hour	15 (24.6%)
1-2 hours	4 (6.6%)
2-3 hours	1 (1.6%)
Over 3 hours	1 (1.6%)

Since it was already known that NHS staff had limited time availability, participants were asked the following question: *“How long should each risk assessment take to complete?”* Table 5.8 gives these results.

To understand the adequacy of current risk assessment guidance, participants were asked how sufficient they find NHS risk assessment guidance documents. Figure 5.2 illustrates all results.

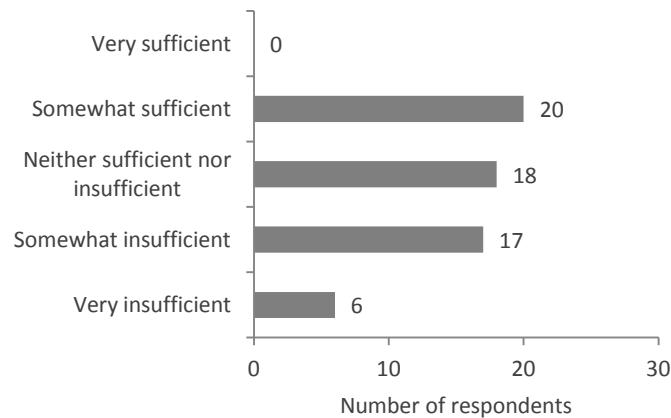


Figure 5.2 Responses for the sufficiency of existed guidance

Respondents were also asked, *“What would encourage those most to be involved in risk assessment?”*, and they were expected to select only one of the statements in Table 5.9 or add one if necessary.

Table 5.9 Responses for factors that encourage respondents to be involved in a risk assessment

What would encourage you most to be involved in a risk assessment?	Number of responses (%)
Understanding value of safety	22 (36.1%)
Less workload	11 (18%)
Training	9 (14.8%)
Support from managers	9 (14.8%)
Recognition from managers	3 (4.9%)
Regulations	1 (1.6%)
Other	6 (9.8%)

While respondents would be encouraged most by understanding the value of safety, almost 10 percent of the respondents provided additional responses.

While some of these additional responses were different from those in the list provided, including ‘confidence’, ‘immediate action when risks are identified’, and ‘financial support’, others only stated multiple options from the predetermined list.

When respondents were asked, “How likely is it that a well-designed framework could guide you to assess risks around you?” the majority of the respondents agreed that a well-designed framework could guide them to assess risks (Figure 5.3).

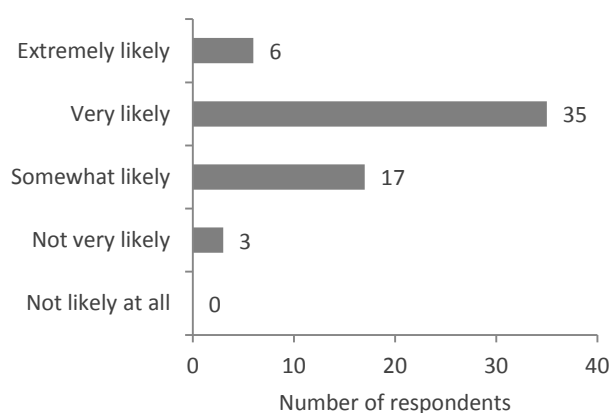


Figure 5.3 Responses for potential contribution of a well-designed framework to guide risk assessment

Lastly, an optional open question was asked: “What things should be considered to improve current risk assessment practice?” Twenty-two participants responded to the question. For instance, a respondent stated:

“I think the basic concept of assessing risk is not well understood and it is often not well linked to action plans to reduce potential risk... Getting beyond the ‘tick box’ mentality of putting things onto the risk register just so we have a long list to show regulators is taking time and effort on the part of those with a good understanding and strong motivation to improve safety”

Six other respondents also pointed out the necessity of providing a clear understanding of risk assessment and why it should be undertaken. Another respondent not only highlighted the concept of risk assessment, but also the regulatory pressure that organisations face and the necessity for a better culture

within organisations. Similarly, two other respondents claimed that risk assessment was:

“Often viewed as a tick-box exercise with limited feedback to staff... They need to share learning, too many organisations are still brushing things under the carpet, and there is very little shared learning.”

“Risk is misunderstood, most NHS organisations are not aware of ISO 31000 although it's been in place since 2009. Unclear objectives and risk assessment is rarely linked to them.”

Additionally, a respondent stated that risks assessments tend to be conducted in response to change, with less focus given to existing risks.

“The main missing factor in risk assessment is the concept of risk balance. Often the risks of changing things are assessed (an impact assessment) without balancing thought about the risks of not changing.”

Of the remaining respondents, four stated the necessity of risk assessment training to improve current risk assessment practice; four mentioned guidance and legislations to be followed; and one pointed out the need for transparency without fear of consequences.

5.3.3 ANALYSIS OF THE QUESTIONNAIRE DATA

Evidence so far reveals that participants might give different responses depending on professions, organisation type and perceptions. A chi-square test was therefore conducted to analyse whether the attributes interact in some way or were independent based on the organisation type, the frequency of involvement and job title. However, the analysis reveals that there was no statistically significant difference yielded between any two variables. For instance, a chi-square test was conducted to reveal differences between the responses of clinical and non-clinical staff on the sufficiency of existing guidance, and a p value of 0.93 was found. In other words, there is no statistical difference

between the responses of clinical and non-clinical staff in relation to their views on the sufficiency of existing risk assessment guidance. The lack of any relationship could also be due to the small sample size.

Findings from the questionnaire indicate that the respondents' aim in undertaking risk assessment is predominantly to assess patient harm and to register a risk. Arfanis *et al.* (2011) also found that healthcare staff often determine risk in relation to the well being of patients. However, respondents also described multiple other aims in undertaking risk assessment such as to support service and to increase professional performance. This indicates that risk assessment in hospitals covers a variety of topics.

Not surprisingly, RCA was most often selected as a method to assess risks since NHS hospitals are expected to use RCA after each serious incident (Peerally *et al.* 2016). However, it is often used in hospitals to investigate '*What went wrong?*' rather than '*What similarly might go wrong?*'. Indeed, considerably fewer participants selected the methods and techniques that enable proactive risk assessment (e.g. FMEA and HAZOP), which might indicate that current risk assessment practice in hospitals tend to be reactive rather than being proactive.

Although good risk assessment is considered to be a part of everyday practice with involvement of a multidisciplinary team (Woodward *et al.* 2004; Illingworth 2015a), results show that risk assessment is not part of everyday practice given the respondent's frequency of involvement in risk assessment. Most of the questionnaire respondents' stated that they conduct a risk assessment once in every few months or less. This could be due to limited time availability of healthcare staff, an issue which was revealed in both questionnaire and interview results. Indeed, risk assessment can be considered to be a time-consuming bureaucratic exercise (Illingworth 2015b; Vincent *et al.* 2013). However, this could also be due to the lack of perceived value of the risk assessment.

In summary, the findings of the questionnaire supported the previous findings of this research as well as findings from the literature review. Risk assessment is mostly conducted to assess harm, to register risks and to meet responsibilities;

most respondents would conduct risk assessments following an incident, most often by using the RCA; risk assessment is not an everyday practice; the desired duration of time for risk assessment was mostly up to 1 hour; existing guidance can be considered to be insufficient; and almost all respondents believe that a well-designed risk assessment framework would guide them in assessing risks.

5.4 EVIDENCE FROM THE ANALYSIS OF A RISK MANAGEMENT SYSTEM

So far, the findings represent current practice as healthcare staff describe it. However, what they described might still be different from what they actually do. To address this gap, a risk management system that provides data for risks and incidents from a single Trust was investigated.

5.4.1 METHODS

Risk management data from a single acute Trust, Addenbrooke's Hospital, were analysed after gaining access to the Trust's risk management system, which constitutes the risk register of operational risks, and incident reporting systems. These were accessible through the use of Trust's intranet system. While the risk register system aims to diagnose potential problems, the incident reporting system aims to learn from experiences to prevent the occurrence of similar events.

Both the risk register and incident reporting system data were filtered for risks or incidents that occurred in the same fixed time period, between 01/01/2014 and 01/01/2015. Following that, the collected data were analysed in terms of *the number of risks and incidents that were reported, the type of information that was reported, the type of risk or incident, and their risk levels.*

To categorise the type of risk or incident, the Trust's own risk categorisation scheme was used. The Trust classifies risks as clinical risks (e.g. delayed discharge,

blood wastage and drug errors), organisational risks (e.g. lack of beds, staff recruitment and lack of training), health and safety risks (e.g. lack of fire fighting equipment, stress management and slippery floors), project management risks (e.g. lack of funding, regulatory risks and lack of stakeholder support) and information risks (e.g. breach of confidentiality, poor data quality and weak passwords).

5.4.2 RESULTS FROM THE RISK MANAGEMENT SYSTEM

The results from these two risk management datasets show that there were 470 risks registered in the risk register system between 2014 and 2015, and 8733 incidents reported in the incident reporting system for the same time period. Figure 5.4 shows these results in terms of the number of risks and incidents reported, and their identified risk levels.

As seen in Figure 5.4, more incidents were reported than risks within the same time period. Even if it is assumed that a different individual registered each risk, only 5.6 percent of staff (470 of 8395 staff) registered a risk within the period of a year. If the same assumption is applied to incidents, each staff member reports on average at least one incident per year.

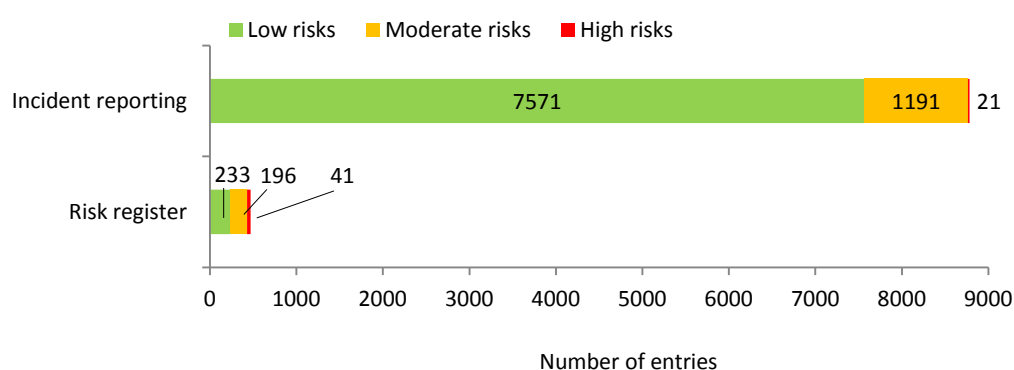


Figure 5.4 Number of reported risks and incidents between 2014 and 2015

Additionally, results reveal that most of the reported incidents and risks were categorised as low risk. However, a significant number of risks were registered as moderate risks (41.7%), and a considerable number of high risks were registered

(8.7%). Conversely, the incident reporting system predominantly defined incidents as low risk (86.2%) with only a very small percentage of incidents being defined as high risk (0.2%).

The risk register and incident reporting systems were reviewed in more detail to reveal the type of risks that were registered in these databases. Figure 5.5 illustrates the risk register system data by considering the risk levels and the risk categories. The Trust used the risk matrix M4 (see Figure 4.2), which has three coloured bands.

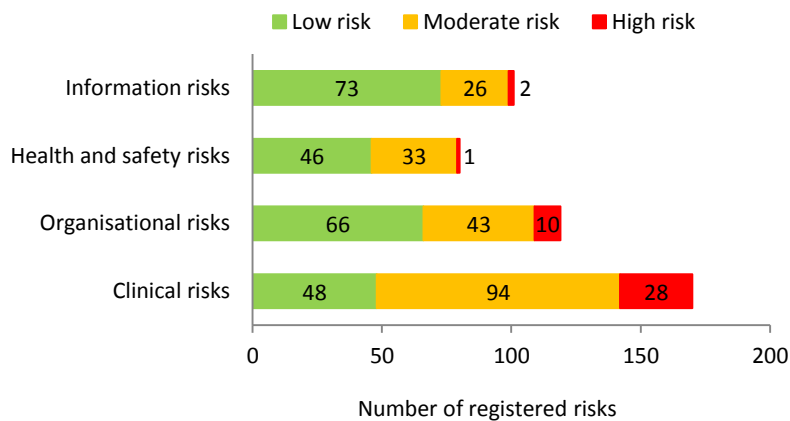


Figure 5.5 Number of registered risks between 2014 and 2015

As shown in Figure 5.5, most risks were defined as clinical risks, which is not surprising since the main function in a healthcare Trust is to deliver care. In terms of the level of the risk, most of the risks were assigned to the low risk level in all risk categories, except clinical risks.

To provide some examples of registered risks, all high risks for which management was completed ("*closed high risks*") (n=17) were further reviewed. These registries included the details of assessor, assessed department/ward, task being assessed, hazards, likely adverse affects, people at risk, existing control measures, risk score, further actions, residual risk score, review data and the details of risk lead to approve the risk entry. Table 5.10 provides a summary of details for these closed high risks.

Table 5.10 Details of seventeen closed risk registries

Reporter	Ward/ Department	Hazards Related to	Risk Score Before and After	Targeted Closure Time	Achieved Closure Time
Team leader	Theatres	Equipment	16-16	1 day	1 year
Senior sister	ENT surgery	Equipment	16-4	15 days	6 months
Unit leader	Theatres	Equipment	25-6	8 days	6 months
Operations manager	Theatres	Scheduling	16-12	9 days	9 days
IT system manager	Pathology	IT system	20-2	6 months	14 months
Senior team leader	Information management	IT system	25-12	14 days	2 months
Team leader	Theatres	Equipment	20-4	7 weeks	7 weeks
MRI manager	MRI Unit	Scheduling	20-9	4 months	4 months
Operations manager	Urology	Equipment	16-8	1 week	5 weeks
Clerk	Eye Clinic	Scheduling	16-8	2 months	Combined into another risk
Consultant surgeon	Theatres	Equipment	20-5	1 month	1 month
Senior audiologist	ENT Clinic	IT & schedule	20-20	6 weeks	6 weeks
Senior clinical nurse	Theatres	Equipment	16-4	5 months	6 months
Team leader	Theatres	Equipment	16-4	1 day	6 months
Senior sister	ENT surgery	Staffing	20-12	4 months	8 months
Quality manager	Haematology	IT, staffing & equipment	16-8	3 weeks	23 weeks
Senior sister	Hepatology	IT & procedure	20-6	4 days	6 months

Findings from all closed high risks demonstrated that risks were most often (n=15) defined by the senior staff, team leaders or operation managers, and risks were most often (n=7) registered by the theatre staff.

In relation to the description of tasks being assessed, it was often a specific existing problem that was identified (n=13) rather than a potential problem (n=4). For instance, the descriptions of the task being assessed included *“unsafe and unworkable work flows in EPIC”*, *“lack of availability stack system for endoscopic transphenoidal cases”*, *“use of equipment no longer supported by manufacturer”* and *“operation issue: no timescale and lack of coordination of hardware and software installation prior to e-hospital go alive date”*.

The hazard presented by the risk entry was selected from a predetermined list in all seventeen reviewed cases. However, some risk entries also included manually added hazards. In total, of the 56 hazards listed, 6 were manually added such as *“patient cancellation due to equipment failure”* and *“delayed clinic appointments can result in permanent visual deterioration”*. The most commonly-selected predetermined hazards were *“targets workload”* (n=10), *“lack of resources funding”* (n=6), and *“inadequate staffing /skillmix”* (n=4).

The majority of these closed high-risk entries were equipment related (n=9). For instance, an issue with an old neuro nerve monitor was reported and the hazard was identified as *“patient cancellation due to equipment failure”*; likely adverse affects were determined as *“patient safety, failure to meet targets and quality of service affected”* and existing control was described as *“Equipment rep has given a loan nerve monitor when ours is at repair”*. For the required actions, *“the replacement with a new monitor”* was recommended. Another risk entry identified the issue as *“the availability of a flexible nasendoscope/headlight light source”*, which could lead to delays in the treatment process and in turn the discharge time. For this specific issue, a hazard was identified as *“lack of resources funding”*, likely adverse affects were defined as *“patient safety, harm/injury, failure to meet targets, quality of service affected and bad publicity”*, and existing control was defined as *“Light source borrowed from clinic during bank holidays periods and patients referred to clinic during clinic hours where necessary”* and the action recommended was purchasing a functioning light source.

The findings also show that only 2 out of 17 risk registries retained the same risk score after action; 10 dropped to the moderate risk level and 5 dropped to the low risk level. The significant drops were often in relation to equipment and fell mostly because new equipment was purchased. While most of the rest still fell, it is not clear whether this was due to a natural change in the risk, or due to the implementation of the recommended actions.

Furthermore, the majority of risk entries (n=12) were closed after target closure times had passed. While the average targeted closure time for these 17 closed-

high risks was estimated to be 53 days, the average closure time was 140 days. Risks were managed over a much longer time period than expected.

Turning to the incident reporting data, risk levels were assessed by the Trust to each reported incident in order to facilitate prioritisation. Incidents are summarised by risk category and potential risk level in Figure 5.6.

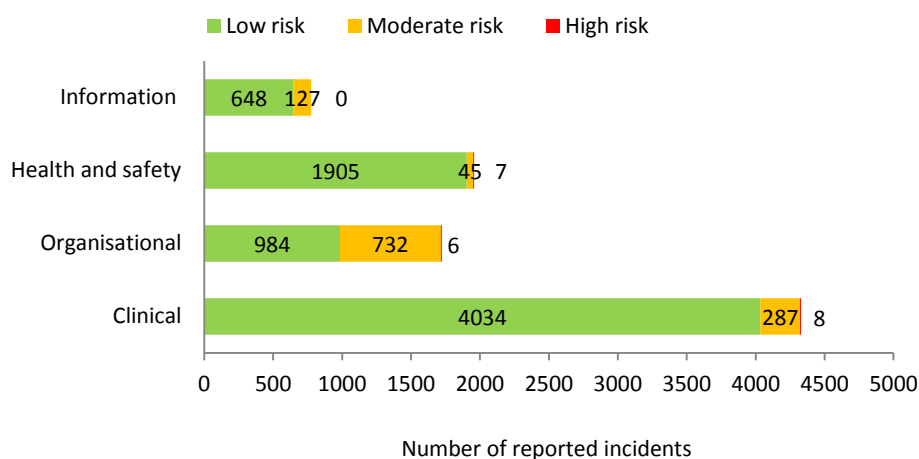


Figure 5.6 Number of reported incidents between 2014 and 2015

As it can be seen, by far the most common incidents were low-risk clinical incidents and, following that, low-risk health and safety related incidents. To gain additional insight, Figure 5.7 illustrates the most commonly-occurring incident types, those that were reported more than 100 times, by category.

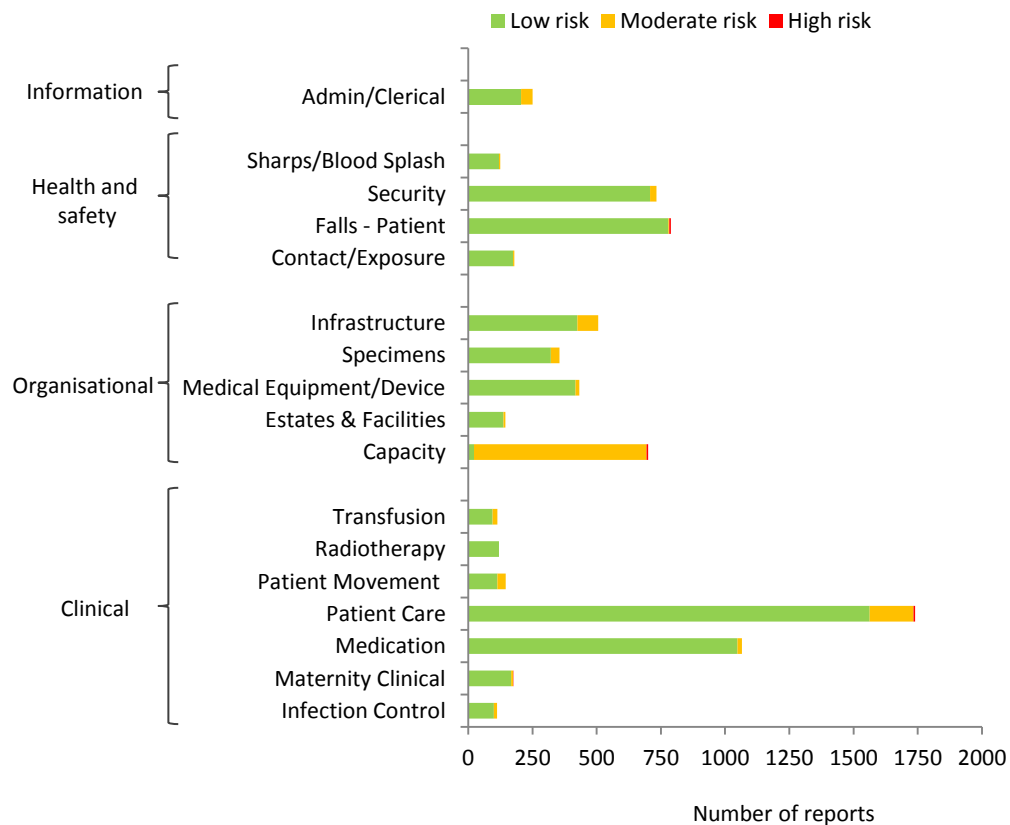


Figure 5.7 Details of reported incidents between 2014 and 2015

The majority of these reported incidents were related to patient care, medication, patient falls, security and capacity. For instance, *treatment delay* (n=265) and *pressure ulcers* (n=240) were the most commonly reported incidents in terms of patient care related incidents; *CD discrepancy* (n=98) and *prescribing-omission* (n=68) were the most commonly reported incidents in terms of medication related incidents; *emergency assistance request* (n=146) was the most commonly reported incident in terms of security related incidents; and *staffing/workload* (n=616) was the most commonly reported incident in terms of capacity related incidents.

5.4.3 ANALYSIS OF THE RISK MANAGEMENT SYSTEM

The findings from the Trust's risk management system indicate that risk assessment does not receive as much attention as incident reporting. When risk assessment is in place, risks are often related to ongoing issues.

It is interesting to note that, risks are likely to be scored higher than incidents. This could be as a result of the blame culture in healthcare organisations (Hutchinson et al. 2009). Healthcare staff might fear revealing incidents that have resulted in more severe harm in order not to be blamed or punished for causing it. Indeed, blaming and an inadequate safety culture have been criticised in the healthcare literature by many researchers (Youngberg 2011; DoH 2000; Carroll and Edmondson 2002; Kaissi 2012). Equally, it could be that people simply choose a higher risk score when identifying risks because there is no reason to be blamed in highlighting something that has not happened yet. However, evidence so far has shown that a risk might be scored higher than it should be in order to attract more attention from the managerial levels. Yet, interestingly, incidents were reported significantly more often than risks.

Turning to the reviewed risk register data, a number of challenges were observed. Although the risk register system is designed to identify tasks being assessed, hazards and existing controls, it tends to be misused or insufficiently used by assessors. For instance, most of the tasks (13 out of 17) were a very specific on-going problem; hazards were often described as generic risk sources (10 out of 17) or as consequences; causes were often not described (11 out of 17) and when it was described, only a single cause was identified; and existing controls tend to be explained by focusing on either the prevention of the undesired event only or on minimising its consequences only. As a result, the questions *“What is being assessed?”*, *“What are the potential undesired events?”*, *“What could contribute to their occurrence?”* and *“What are the existing controls in the system?”* were not clearly answered.

Additionally, it was found that the risk register system can be used as a request form from front line staff to managerial bodies. For instance, a risk was registered by identifying the risk as *“harmonic scalpel required”*, selecting the hazard from a predetermined list as *“lack of resources/funding”*, scoring the risk as 9 (L:3 x C:3) and completing the actions required section as *“insufficient equipment to meet increased demand of theatre activity”*. Such interpretations of risk assessment

provide evidence supporting the view of a critical report that *“risk registers tend to be backward-looking data-collection exercises”* (Illingworth 2015a).

There were also a number of challenges identified in relation to the design of the risk register system. For instance, the risk register system provided a predetermined list of hazards that assessors could select, or they could enter one manually. However, not all of the selected hazards seemed to help identify the specific risk sources. For instance, lack of resource funding was identified as a hazard for the task associated with *“the availability of a flexible nasendoscope/headlight light source”*. Furthermore, the system did not enable the assessors to determine the causes of the potential undesired events. Since the potential causes and the overall system to be assessed often were not described, it can be difficult to work out the all controls needed to prevent or minimise the risks. In turn, there is a potential for inadequate risk assessments to be conducted.

In summary, the review of the risk management data shows that risk management is predominantly reactive. Even the proactive risk register system tends to be used as a reactive data collection system by defining existing issues. The risk register forms can be inadequately completed through not providing much detail to help in the management of the risks and by focusing on specific on-going issues rather than the potential undesired events within the system to be assessed. All of the reviewed risk entries, except one, provided very few details. While some of these problems might result from a poor design of the risk management system, some might be due to misuse or misunderstanding stemming from a lack of staff training on risk assessment. In essence, the evidence so far demonstrates the need to improve current risk assessment practice.

However, it must be noted that the dataset analysed may not reflect all risk data in the Trust. Also, different Trusts might register risks by providing different information with a different degree of sufficiency.

5.5 EVIDENCE FROM THE REVIEW OF THE BOARD ASSURANCE FRAMEWORK

Risks are categorised as *operational* or *strategic* (Chapter 4). While the previous section focussed on operational risks, this section investigates strategic risks to understand the overall risk assessment practice better. Strategic risks relate to the achievement of organisational objectives, and such information is provided by the Board Assurance Framework (BAF). Therefore, this section reviews a number of BAF documents from multiple hospitals.

5.5.1 METHODS

This study reviewed 34 Board Assurance Frameworks (BAF) in order to explore the strategic risks reported by hospitals in NHS England. The 34 hospitals were purposively selected from the 160 NHS England acute hospitals to ensure different hospital types in different regions were adequately represented. BAF reports were collected from the selected hospitals' websites. Table 5.11 provides information about the hospital type (acute specialist, acute teaching, large, medium and small Trusts) by region (North, Midlands and East, London, and South).

Table 5.11 Characteristics of the selected hospitals

Hospital Type	North (n=10)	Midlands and East (n=9)	London (n=5)	South (n=10)
Acute specialist (n=2)	1	-	-	1
Acute teaching (n=8)	2	2	2	2
Large (n=10)	4	3	1	2
Medium (n=9)	2	3	2	2
Small (n=5)	1	1	-	3

After gathering BAF reports from the 34 selected hospitals, their top five (i.e. highest) risks were listed and risks were categorised as clinical risks (e.g. delayed discharge, blood wastage and drug errors), organisational risks (e.g. lack of beds, staff recruitment and lack of training), health and safety risks (e.g. lack of fire

fighting equipment, stress management and slippery floors), project management risks (e.g. lack of funding, regulatory risks and lack of stakeholder support) and information risks (e.g. breach of confidentiality, poor data quality and weak passwords).

5.5.2 RESULTS FROM THE BAF REPORT REVIEWS

The hospitals' top five strategic risks were reviewed from the collected documents. Figure 5.8 demonstrates the strategic risks that were defined at the board level by at least 3 hospitals.

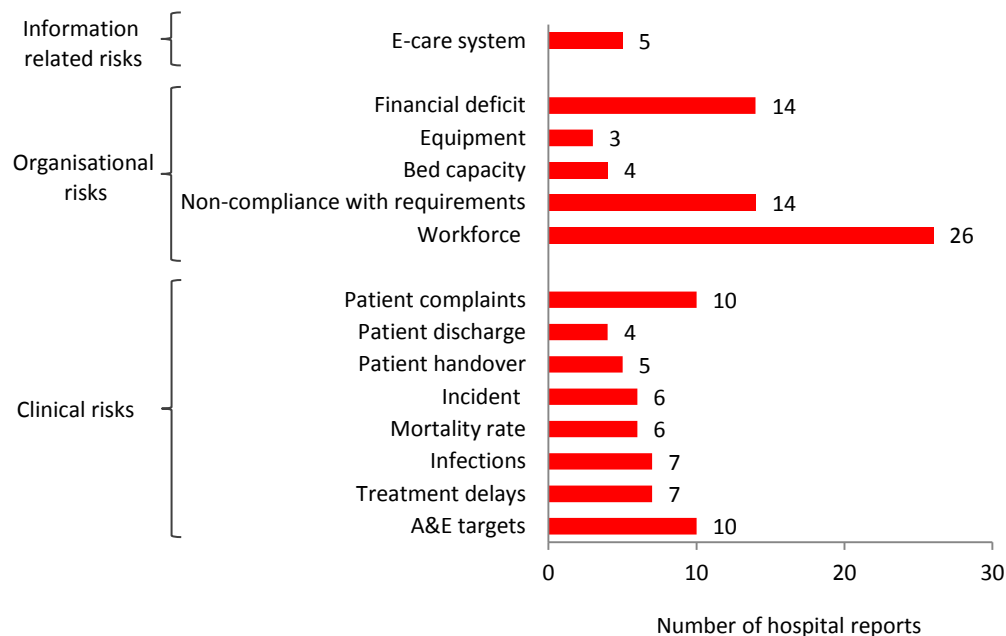


Figure 5.8 Details of strategic risks

The results reveal that most of the strategic risks were clinical and organisational. It was clear from the results that the majority of hospitals (n=26) reported a strategic risk with relevance to “workforce”. Additionally, “financial deficit” and “non-compliance with requirements” were also found to be frequently reported.

As expected, the strategic risks reported reflect major problems that occur in the organisation, such as *staff capacity*, *finance*, *mortality rate*, *infection* and *A&E waiting time*. Similarly, Schmidtke *et al.* (2017) listed board level defined quality

and safety issues, as “*waiting times*”, “*incident reports*”, “*infections*”, “*mortality*”, “*pressure ulcers*”, and “*falls*”.

Additionally, it was observed that regulatory targets and reported incidents influence the identification of strategic risks. For instance, failure to meet A&E targets is identified as a strategic risk, where a 4-hour wait in A&E from arrival to admission is one of the often mentioned regulatory targets (Parkin 2016).

Strategic risks can be identified from the risk register and incident reporting data as well as by considering regulatory targets and ongoing repetitive issues within the hospitals (e.g. workforce and bed capacity). Most importantly, finance related risks were revealed as part of strategic risks whereas they were not seen in the risk register or incident reporting systems.

5.6 DISCUSSION

This chapter presented evidence from a range of sources to view and analyse the big picture for current risk assessment practice as well as to reveal the practical experience of NHS staff of risk assessment practice, to define existing challenges and to highlight the need for the improvement of the current risk assessment practice.

The findings of this chapter show that ‘*work as described*’ is not the same as ‘*work as done*’. Perhaps, ‘*work as done*’ can be divided into ‘*work as done as described*’ and ‘*work as done as observed*’, which were found to be different too. For instance, risk assessment policies are assumed to be read and followed by healthcare staff, and healthcare staff would indeed know where to find such documents, but such documents tend not to be read by them. Furthermore, the risk register system is assumed to be used to record all risks and diagnose problems. However, it can be used to garner attention from higher managerial-levels in relation to an ongoing issue. Moreover, it is recommended that risk matrices be used in risk assessment, and, indeed, they are used when one is

undertaken. However, while the use of risk scoring guidance is also advised, this might not happen in practice. Risks can be scored subjectively.

The findings also reveal that not all healthcare staff conduct risk assessments in the same ways and using the same tools and techniques. This might be one of the reasons why there was lack of evidence in the literature in relation to the overall current risk assessment practice in hospitals. Based on the findings collected so far, current risk assessment practice in NHS England hospitals is conducted through (1) individual patient-based risk assessment, (2) operational risk assessment, and (3) strategic risk assessment. Depending on the type of risk assessment, risks can be recorded onto different databases. Figure 5.9 clarifies current risk assessment practice.

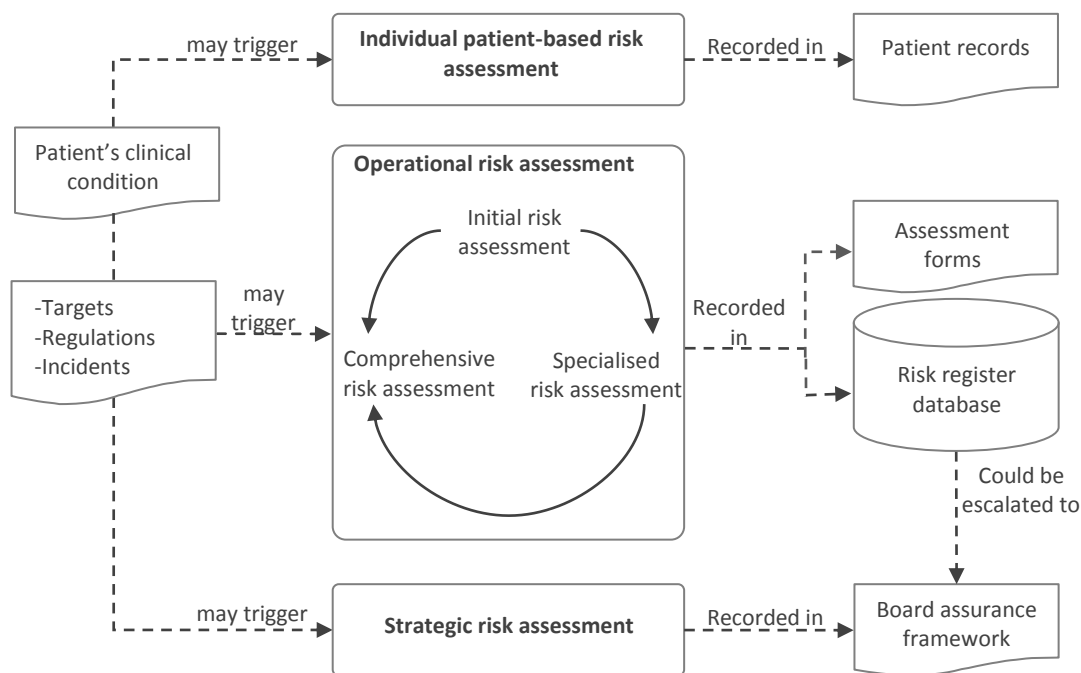


Figure 5.9 Current risk assessment practice in hospitals in NHS England

Individual patient-based risk assessment is conducted to manage risks that threaten the safety of individual patients. It is usually conducted through clinical team discussions by relying on professional experience. Mental Health Trusts are strongly encouraged to screen risks for each administered patient (DoH 2010). Following that, specific risks can be assessed further such as the risks of suicide,

self-harm and violence towards others (O'Rourke and Bird 2001; DoH 2007). After completion of the assessment, findings are documented in the patient record system.

Operational risk assessment is conducted to manage all operational risks that threaten individuals, organisations, and the environment. It can be conducted in three ways, which are initial risk assessment, specialised risk assessment and comprehensive risk assessment.

Initial risk assessment allows assessors to recognise major risks and the need for further assessments. The main goal is to allocate resources by focusing on the most important risks (BSI 2010). Initial risk assessment is usually conducted through the use of an assessor's judgement or a Trust risk register form. Initial risk assessment is usually conducted for the assessment of operational risks. Most of the Trusts encourage their staff to record all operational risks onto the risk register system.

Specialised risk assessment refers to the assessment of specific risks such as patient falls, violence and aggression, VTE, suicide/self-harm and display screen and working environment. Specialised risk assessment forms, techniques, checklists and assessors' judgments are used to conduct such assessments. The *Best Practice in Managing Risk* document provides a number of tools to assess some of these specific risks (DoH 2007). These indicate, for instance, a number of tools provided for the assessment of patient falls such as the STRATIFY scale, the Morse Fall Scale (Morse et al. 1989) and the Hendrich Fall Risk Model (Hendrich et al. 1995).

A comprehensive risk assessment can be conducted following specialised as well as initial risk assessments. The comprehensive risk assessment is an in-depth risk assessment that involves a multidisciplinary team and uses systematic risk assessment tools. Multiple risk scenarios can be discussed regarding the system to be assessed, and better action plans can be determined to achieve objectives as well as to improve loss control (BSI 2000). Although it is not possible to assess every single risk through comprehensive risk assessment, such an assessment

should be conducted when there is a change in the system to be assessed (NPSA 2006), the system or task is dynamic and complex (Hollnagel et al. 2013), incidents are unexpected, or potential harm or loss is severe (NHS England 2015d).

Strategic risk assessment is conducted to manage the most significant risks to prevent organisations to achieve their objectives (Frigo and Anderson 2009; DoH 2003). Board level staff assess strategic risks and the findings are documented in Board Assurance Frameworks (DoH 2003). Strategic risks may also consider unsolved operational risks and significant incidents.

Turning to the findings from this chapter, there are a number of challenges identified in assessing risks in hospitals, predominantly due to the fundamentals and use of risk assessment practice. Table 5.12 summarises the challenges observed via the conducted studies.

Table 5.12 Challenges for the current risk assessment practice

Source	Challenge
Evidence from the practical experience of NHS staff	<ol style="list-style-type: none"> 1. Subjective judgements made when assessing risks 2. Lack of use of prospective hazard analysis techniques 3. Subjective risk scoring 4. Lack of consideration of additional factors when prioritising risks 5. Misuse of risk terms 6. Lack of sufficient training on risk assessment 7. Time requirement for assessing risks 8. Lack of communication between staff about risk assessment 9. Lack of follow up after completing risk assessment 10. Lack of perceived value of risk assessment
Evidence from the analysis of risk management systems	<ol style="list-style-type: none"> 1. Only a small number of NHS staff record risks in risk registers 2. The risk register system can be used to garner attention from higher managerial levels. 3. Insufficiently completed risk assessment forms 4. The system to be assessed is not described well 5. Contributory factors are often not stated 6. Registered risks tend to reflect an ongoing problem 7. The management of risks is completed significantly later than the targeted time

To address these challenges, a number of potential recommendations can be made. For instance, a new risk assessment technique could be developed for use

by healthcare staff in order to conduct more reliable risk assessments; the safety culture could be improved to encourage healthcare staff to be more involved in risk assessment; or better safety training programmes could be designed and provided. However, most of the problems identified were in relation to the fundamentals of risk assessment and its use.

Therefore, this research aims to design a better risk assessment approach to provide better guidance on the concept of risk assessment. To do so, a risk assessment framework will be designed by learning from the good risk assessment practices prescribed in safety-critical industries and by addressing the challenges of current risk assessment practice. The framework will be designed through building on the existing risk assessment framework as in Figure 5.10. The inputs and outputs at each step are indicated by arrows and the question marks indicate areas for clarification.

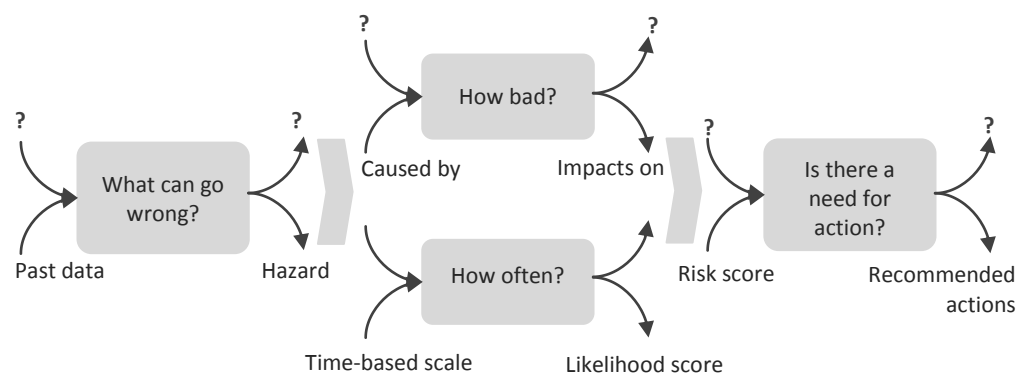


Figure 5.10 Risk assessment framework to be designed

Designing a framework can support the front-line staff to undertake more effective risk assessments. A successfully designed framework also has an important role in decision making, as in risk assessment (Johnson 2012). Participants of this research also highlighted the potential value of a well-designed risk assessment framework.

In this chapter, eight requirements were captured from interviews and questionnaires as well as through the review of documents and a risk management system in Table 5.13. Indeed, studying documents and software

systems are held to be invaluable techniques to elicit both user and domain knowledge requirements (Maciaszek 2007).

Table 5.13 Requirements captured from the actual practice

Requirements	Justification	Source
1. Ordinary language should be used in risk assessment	To ensure everyone can understand the terms used in risk assessment	Interviews (page 98)
2. Improved approach should fit on an A4 sheet	Many-paged documents do not get attention by the healthcare staff	Interviews (page 97)
3. Framework should support a quick risk assessment	Limited time availability of the clinical staff and their willingness to attend to time-intensive risk assessments	Interviews (page 99) and questionnaire (Table 5.8)
4. Risk assessment should be systematic	To ensure assessors follow a clear risk assessment process	Document analysis (page 67) and interviews (page 93 and 94)
5. Framework should be easy to use	To ensure that everyone can use the framework easily	Interviews (page 97) and questionnaire Table 5.6
6. Framework should be adaptable to all contexts and it should guide the assessment of all risk types	To ensure that the framework can be used by different professionals and for different purposes	Interviews (page 97)
7. Framework should be accessible	To ensure that everyone can access the framework	Interviews (page 97) and observations
8. Framework should be compatible with other risk assessments tools and methods	To ensure the framework can be combined with other tools and methods that are currently used	Interviews (page 97) and observations

In Table 5.13, requirements are listed for the use of the researcher to design the proposed framework. Three researchers had multiple group discussions to list the requirements. However, it should be noted that further studies could have added additional requirements. Indeed, further requirements are identified in the next chapter through the use of different sources.

5.7 SUMMARY

This chapter investigated the actual risk assessment in hospitals in NHS England through the use of mixed methods. The findings in this chapter reveal that risk assessment in hospitals is conducted in three different ways, which are individual

patient-based, operational and strategic risk assessments. The findings, however, also highlight a number of challenges regarding current risk assessment practice in hospitals. These challenges were predominantly in relation to the fundamentals and the use of risk assessment. Thus, this research sets its focus on designing a risk assessment framework to support healthcare staff in undertaking risk assessments. To do so, a number of requirements for a better risk assessment framework were identified.

CHAPTER 6

PROPOSED RISK ASSESSMENT APPROACH

6.1 INTRODUCTION TO PROPOSED APPROACH

Earlier chapters have investigated current risk assessment practice, highlighted problems with current risk assessment practice, revealed the need for improving the current risk assessment practice, and outlined the requirements captured from the actual practice for a better risk assessment framework.

This chapter proposes a risk assessment framework to guide effective risk assessment in hospitals. To design the proposed approach, further requirements are captured by determining good risk assessment practice. A risk assessment framework is then designed by considering all requirements for use by healthcare staff to assist them in risk assessment. In turn, this chapter thus proposes an answer to the main research question: *“How can current risk assessment practice be improved to ensure safety in hospitals?”*

6.2 METHODS

The Vee developmental model was used to design the proposed risk assessment framework. The Vee model starts with understanding user needs, which are translated into system requirements and detailed design (Forsberg and Mooz 1991; Blanchard 2008; Grady 2016). In so doing, the system is decomposed into elements until all the lowest level details are specified, and all requirements are defined in relation to components, subsystems and the system (Grady 2016).

The process of above can be done through requirements engineering, which involves requirements elicitation (discovery of the requirement), the analysis of conflicts and inconsistencies, requirements specification (documentation of the requirements descriptions), and validation (ensuring the quality of the requirements) (Sommerville and Sawyer 2003). A developed system is then designed in accordance with all requirements. After that, verifications of component, sub-systems and the system follow in order to prove that the developed concept meets its specifications (Grady 2016). The model ends with user validation to prove that it satisfies the user needs (Forsberg and Mooz 1991).

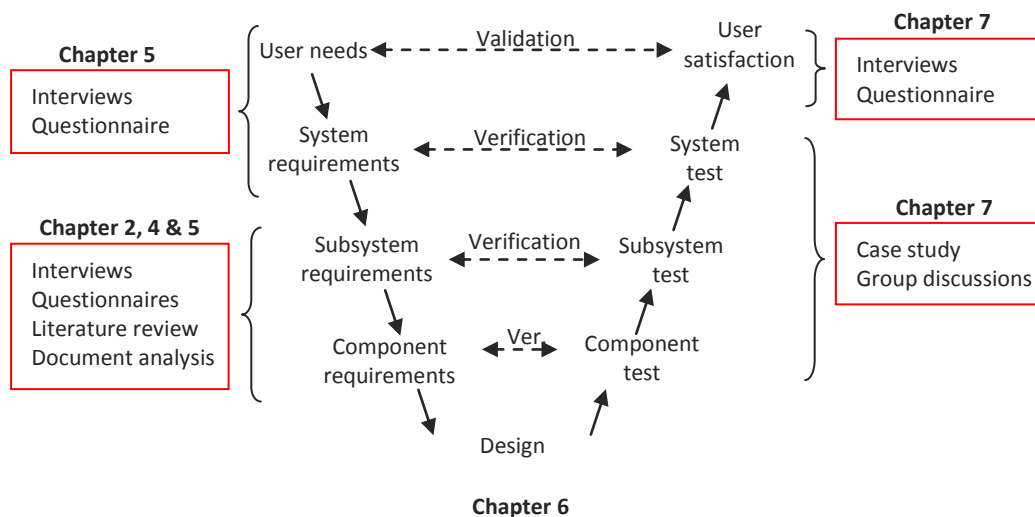


Figure 6.1 Vee model to develop framework adapted from Grady (2016)

Figure 6.1 illustrates the Vee model adapted to design a risk assessment framework by highlighting methods applied at each stage. The model starts with

understanding user needs, which were acquired through interviews and questionnaires and were presented in Chapter 5. Requirements were elicited from the interviews, questionnaires, and an extensive literature review as well as documentation analysis from hospitals and prescribed good risk assessment standards from other industries. An analysis was then conducted by three researchers to ensure that there are no conflicted and inconsistent requirements. Following that, requirements were listed and evaluated by the same three researchers in order to help the researcher (GKK) to design the proposed approach. Finally, multiple concepts were considered based on the requirements captured and one of these was selected to be developed, and, then, to be tested. While this chapter provides the results of the left-hand-side of the Vee model, the next chapter provides the results of the right-hand-side of the Vee model to evaluate the proposed approach.

6.3 REQUIREMENTS OF THE PROPOSED FRAMEWORK

Good risk assessment practice was described in Chapter 2. Considering the inputs and outputs of good risk assessment practice, key elements of the risk assessment process are listed in Table 6.1.

In Table 6.1, the risk assessment is divided into three parts: risk identification, risk analysis and risk evaluation, and the key elements are characterised as being input, output and supportive elements. Requirements are captured by determining these elements and supported by the previous findings of this study. The requirements are numbered in Table 6.1 in square brackets.

Table 6.1 Key elements of risk assessment (the requirement captured)

Elements	Risk Identification	Risk Analysis	Risk Evaluation
Inputs elements	1) System description [R1] <ul style="list-style-type: none">– Aims– Elements– Interactions between elements– Boundary– Context	1) Existing controls [R8] <ul style="list-style-type: none">– Preventative– Detective– Recovery	1) Risk acceptance principles [R11] <ul style="list-style-type: none">– Application of codes of practice– Comparison with similar reference practice– Explicit risk level
	2) Risk sources [R2] <ul style="list-style-type: none">– Patient– Staff– Task– Communication– Equipment– Control actions– Organization– Environment	2) Consequences on [R6] <ul style="list-style-type: none">– People– Organisation– Environment	
	3) Nature of the risk [R3] <ul style="list-style-type: none">– Known– Unforeseen	3) Likelihood measurement [R8] <ul style="list-style-type: none">– Time-based– Probability-based– Nominal	
Outputs elements	1) Event [R4] <ul style="list-style-type: none">– Event description– Links with other events	1) Risk level [R8], [R11] <ul style="list-style-type: none">– Likelihood (s)– Impact (s)	1) Risk tolerability [R11] <ul style="list-style-type: none">– Intolerable– ALARP– Tolerable
	2) Contributory factors [R5]	2) Detectability [R12]	2) Risk priority [R12]
	3) Consequences [R6] <ul style="list-style-type: none">– Immediate effects– Knock-on effects	3) Vulnerability [R12]	3) Initial control measures [R13] <ul style="list-style-type: none">– Preventative– Detective– Recovery
	4) Risk categories [R7] <ul style="list-style-type: none">– Clinical– Organisational– Health and safety– Project management– Information	4) Speed of onset [R12]	
Supportive elements	Assessment methods (historical data, expert opinion, techniques), guidance, assessment principles, and communication and consultation [R14, 15]		

Evidence gathered so far demonstrates that risk identification tends to be conducted with an insufficient consideration of the system to be assessed in the first place (see section 5.4.2). This could be due to the fact that risks tend to be

identified one at a time without consideration of other relevant risks within the system. However, having a clear understanding of the system is essential for risk assessment (Redmill et al. 1999). The system description is an initial step for the most widely used prospective hazard analysis techniques such as FMEA and HAZOP (BSI 2010). Therefore, the first requirement for the proposed framework is:

[R1]: The system should be described prior to the assessment.

A clear system description should involve the details of the assessment aim, system context, system elements, interactions of the elements and system boundary (ISO 2008; INCOSE 2007). System modelling methods can be used to describe the system; flowcharts are widely used in healthcare (Colligan et al. 2010). Although flow charts might be limited in their capacity to reveal all interactions of the system elements, they are still found to be the easiest and most suitable for use in healthcare (Jun et al. 2010).

Regarding risk identification, risks should be identified at their source (BSI 2009). Hazards or contributory factors can be determined as risk sources (BSI 2009; Simsekler et al. 2015). Observations from current risk assessment practice show that risk sources are often selected from a prepopulated list, with list items which could be too generic or irrelevant to the identified risks. Additionally, it was found that these terms can be easily misused (see section 5.4.2). For instance, a hazard can be interchangeably used with a risk or an undesired event, and a risk source can be determined as a source where risks are first recognised (e.g. incident reports) rather than a source that gives rise to the risk. Thus, the second requirement is defined as follows:

[R2]: A comprehensive list of risk sources should be considered when identifying risks.

In the literature, there have been various lists provided to determine risk sources including the London protocol (Taylor-Adams and Vincent 2004), Systems Engineering Initiative for Patient Safety (Carayon et al. 2006), Reason's accident

causal model (Reason 2000) and the Yorkshire Contributory Factors Framework (YCFF) (Lawton et al. 2012). Simsekler *et al.* (2015) compared multiple classification schemes and generated a risk source classification scheme involving patient, staff, equipment, communication, task, organisation and environment. This research adjusted the risk sources classification scheme by predominantly building on YCFF (Lawton et al. 2012) and also considering the *STAMP approach* (Leveson 2011). The YCFF has been applied in various healthcare settings to describe both latent and active failures (Hernan et al. 2015). The YCFF is built on Reason's model and, therefore, the criticisms of the traditional approaches might also apply here. Hence, a combination of the STAMP approach and YCFF was considered to provide a more comprehensive risk source classification scheme. The STAMP approach determines that accidents occur as a result of a lack of controls in the system. Therefore, this approach takes into account the *control actions* in the system to be assessed. Since these are not included in the existing classification schemes, an adjusted risk source classification scheme including control actions as risk sources is given in Table 6.2.

Table 6.2 Classification of risk sources

Risk Sources	Example
Patient	Clinical condition, physical factors, social factors, psychological factors
Staff	Physical factors, psychological factors, social factors, cognitive factors and knowledge/skills
Task	Unfamiliar task, difficult task and monotonous task
Communication	Poor verbal/written communication, lack of feedback, lack of information
Equipment	Poor design of equipment, equipment not working, inadequate maintenance
Control actions	No actions, unsafe actions, action too late, too early or out of sequence, and action stopped too soon or applied too long
Organisation	Organisational structure, policies/procedures/protocols, staffing/workload, training and safety culture
Environment	Physical environment, external environment (e.g. external authorities and suppliers)

The nature of the risks should be also considered when identifying risks. Risks can be known or unforeseen. BS EN ISO 17776 (2002) recommends the use of risk assessment methods based on the nature of risks. For instance, a checklist and

structured what-if technique can be used for known risks, and FMEA and HAZOP can be used to assess unforeseen risks. Findings from the previous chapters indicate that risks in hospitals often relate to existing issues rather than something that has potential to occur. Indeed, risks are often identified following an incident and, therefore, often it is known risks which are being identified. Thus, the third requirement is:

[R3]: Both known and unforeseen risks should be sought.

A description of an event is one of the outputs of the risk identification process. However, anything could be explained as an event. Therefore, effective event identification requires linking the event with objectives and other relevant events (COSO 2004; BSI 2009). Additionally, events could be identified under different system modes such as normal, degraded and emergent modes (ORR 2015). For instance, monotonous risks are more likely to be identified under the normal system mode and extreme risks are usually identified under the emergent system mode. Observations from current risk assessment practice, however, reveal that risks are identified without linking undesired events with objectives or any other relevant events. This leads to the fourth requirement:

[R4]: An event should be identified by considering objectives and links with other events.

Events occur due to a combination of factors (BSI 2011b). Therefore, consideration of multiple factors can lead to a better understanding of events and, in turn, an improved assessment of risks. However, practical experience has shown that causal explanations are often missed in risk assessments, or that events are explained with a single generic cause. Accidents, in complex systems, occur due to combined mutually interacting factors (Leveson et al. 2016; Klockner and Toft 2015). Thus, contributory factors can be identified by using risk source classification schemes as in Table 6.2. Thus, the fifth requirement is:

[R5]: Contributory factors to events should be identified.

A single event can result in different consequences and their impacts could be on people, the organisation and the environment (ISO 2000). In addition to this, different consequences can be identified by considering both the immediate and knock-on effects (BSI 2009; BSI 2010). Findings from the current practice have demonstrated that *consequence* can be interchangeably used with *effect* or *impact*. While events are identified in the risk register system, less information is provided regarding their potential consequences. Additionally, it is often a single consequence domain that is determined with a main focus on generic immediate effects. This indicates the sixth requirement, which is:

[R6]: Consequences should be identified by considering all impact domains in line with both immediate and knock-on effects.

After identifying all risks, risks should be categorised to manage them more effectively. Observations from current practice have shown that hospitals categorise their risks based on their risk categorisation schemes. For instance, risks are categorised in a Trust as: clinical, organisational, health and safety, project management and information risks. However, different hospitals might use different categories. Indeed, hospitals should adapt the most suitable categories for themselves by ensuring that a risk can only be defined under one category. Therefore, the seventh requirement is:

[R7]: Risks should be properly categorised to help management of all risks.

Having built on the findings of risk identification, the risk analysis process determines existing controls to reveal the real level of risk (BSI 2010; BSI 1996; BSI 2009). Controls can be characterised as eliminative, detective and reductive (BSI 2010; ISO 2012; AFSC 2000). Similarly, Card *et al.* (2014) provides five prompts to determine controls, which are elimination, design controls, administrative controls, detection or situation awareness and preparedness (Card *et al.* 2014a). Reviews of the risk assessment policies and procedures reveal little evidence in relation to such considerations. Indeed, it has been claimed that control actions in hospitals are poorly determined (Card *et al.* 2014a; Card *et al.* 2014b). Thus, the eighth requirement is:

[R8]: All existing controls should be determined to estimate the real level of risk.

The level of risk is estimated through the combination of severity of consequence and likelihood of occurrence (BSI 2010; BSI 2009). In the current risk assessment practice, severity and likelihood measurement scales are provided to estimate risk levels. Each scale is assigned a score from 1 to 5 and a nominal description(s) is provided for each score. Then, these two scores are multiplied to estimate a risk score by the use of risk matrices. However, the use of risk scores and risk matrices is found to be challenging as discussed in Chapter 4. For instance, the risk scores might show little relation to the quantitative value of the risk and risk matrices might assign a risk to the wrong risk level. Therefore, the ninth requirement is:

[R9]: Risk scores should not be the sole basis on which to make risk-based decisions.

Furthermore, the risk analysis process can determine uncertainties, whose detectability can be considered as a factor in measuring uncertainty (NASA 2011). In the analysis of current practice, there was no evidence found to measure uncertainty or discussions around detectability. Actually, observations reveal that the practical risk assessment practice tends to focus on certain existing issues without consideration of potential uncertainties, and current practice itself leads to more uncertainty than it should address. Although consideration of uncertainty might be perceived as an additional burden, it can contribute to risk analysis and prioritisation. Adding this dimension may well help to distinguish between risks at the same risk-level. Thus, the tenth requirement is:

[R10]: Uncertainties should be determined when assessing risks.

Having built on the risk analysis process, the tolerability of a risk is evaluated by comparing the risk level with risk criteria. Studying recommended practice in hospitals has shown that risk matrices are used to estimate the level of risk, and the risk criteria are set with coloured bands on these risk matrices. However, it is

not clear whether or not hospitals use risk matrices to determine the tolerability of a risk. Actually, it is recommended in literature that multiple factors should be considered to make decisions on the tolerability of a risk including the risk level, codes of practice (e.g. standards and legal requirements), and comparison with similar reference practice (ORR 2015). This leads to the eleventh requirement:

[R11]: Tolerability of a risk should be determined based on risk level, codes of practice and comparison with similar reference system(s).

The tolerability of a risk can be categorised as acceptable, tolerable or ALARP and unacceptable. This is often linked with the coloured bands on risk matrices. A lower coloured band indicates acceptable risks, medium band(s) apply to tolerable or ALARP principles and the upper band indicates unacceptable risks (BSI 2010). Yet, as stated, other factors should also be determined. Indeed, risk appetite can be different from one risk to another. For instance, written rules might assign a low or medium risk to an intolerable band. To illustrate this with an example, a risk of a wrong site surgery might be assigned to an undesirable or even tolerable risk band by considering its likelihood and consequence scores. However, this is something that hospitals would not tolerate. Additionally, sometimes a high risk can be tolerated if its benefit outweighs its harm or loss. For instance, chemotherapy itself is a very risky procedure. Yet, its benefit can be more significant than its harm. Therefore, such a high risk could be tolerable. Thus, coloured bands can be linked with risk tolerability since a lower coloured band is generally tolerable, a medium band(s) is generally undesirable or ALARP, and an upper band is generally intolerable.

After the determination of risk tolerability, risks are prioritised for treatment implementation. Risks can be prioritised based on the estimated risk levels, organisational objectives, stakeholder needs, legal requirements, resource intensity for required control actions, detectability of a risk, vulnerability and speed of onset (COSO 2012; EN 2013). In hospitals, risks are predominantly prioritised based on risk scores. However, as mentioned in Chapter 4, using explicit risk scores can lead to random risk prioritisation. To address this challenge, the twelfth requirement is:

[R12]: Risks should be prioritised by considering the level of risk in combination with other factors.

Although the risk evaluation process only considers the tolerability and prioritisation of a risk, consideration of the required actions is also a common practice in healthcare. Since different individuals might take part in the different steps of the risk assessment process, providing an initial list of the required actions may well help managerial level staff when taking over the risk assessment. These actions can be determined as required control actions by considering the same control types as mentioned earlier. Thus, the thirteenth requirement is:

[R13]: Eliminative, detective and reductive control actions should be listed.

Although all requirements in relation to the risk assessment process have been described so far, there are some additional requirements that should also be considered while conducting risk assessments, which were described as supportive elements in Table 6.1. Supportive elements should be used at all stages of risk assessment to achieve effective assessments. These elements include: risk assessment techniques, historical data, expert judgement, and communication and consultation and guidance (BSI 2009; BSI 2010; BSI 2014). In hospitals, risks might be assessed in a variety of ways, including conducting a risk assessment through the use of gut feeling, risk registers, or risk assessment forms. In most cases, historical data are not used to assess risks. However, historical data tend to be collected to fulfil legal requirements. While the healthcare staff often use professional judgement, there is little evidence found demonstrating strong communication and consultation between healthcare professionals. Thus, the fourteenth requirement is:

[R14]: Risk assessment should be implemented utilising assessment methods as well as communication and consultation at all times.

Furthermore, findings from risk assessments should be well documented for staff to be aware of the assessed risks and to be able to monitor them (BSI 1996; BSI

2010). In hospitals, risks are documented on a risk register database or risk assessment forms. However, it is not clear how many of the assessed risks are documented, how much of this documented information is shared with other people and how many of these documented risks are managed. Yet, observations reveal that risk assessment tends to be conducted as a paper exercise; not all the risks are documented; not all the assessed risks are shared with relevant people and not all the risks are monitored in the scheduled time period. Thus, the fifteenth requirement is:

[R15]: Risks should be documented, findings should be shared and documented risks should be monitored.

The requirements listed so far could help design a risk assessment framework. It should also be mentioned that the list of requirements presented here is not exhaustive, and that it constitutes one approach to addressing the problems identified in this research.

Before moving onto the proposed risk assessment framework, all requirements captured so far in this research are listed in Table 6.3.

Table 6.3 All requirements for the design of the risk assessment framework

Requirement No	Requirement Description	Rationale Behind the Requirement		
		Chapter 2	Chapter 4	Chapter 5
1	The system should be described prior to the assessment	✓		✓
2	A comprehensive list of risk sources should be considered when identifying risks.	✓		✓
3	Both known and unforeseen risks should be sought.	✓		✓
4	An event should be identified by considering objectives and links with other events.	✓		✓
5	Contributory factors to events should be identified.	✓		✓
6	Consequences should be identified by considering all impact domains in line with both immediate and knock-on effects	✓		✓
7	Risks should be properly categorised to help the management of all risks.	✓	✓	✓
8	All existing controls should be determined to estimate the real level of risk.	✓	✓	✓

9	Risk scores should not be the sole basis on which to make risk-based decisions.	✓	✓	✓
10	Uncertainties should be determined when assessing risks.	✓		
11	Tolerability of a risk should be determined based on risk level, codes of practice and comparison with similar reference system(s).	✓	✓	
12	Risks can be prioritised by consideration of risk levels in combination with other factors.	✓	✓	✓
13	Eliminative, detective and reductive control actions should be listed.	✓	✓	✓
14	Risk assessment should be implemented utilising assessment methods as well as communication and consultation at all times.	✓	✓	✓
15	Risks should be documented, findings should be shared and risks should be monitored.	✓	✓	✓
16	Ordinary language should be used in risk assessment			✓
17	Improved approach should fit to an A4 sheet			✓
18	Framework should support a quick risk assessment			✓
19	Risk assessment should be systematic	✓	✓	✓
20	Framework should be easy to use			✓
21	Framework should be adaptable to all contexts and should guide the assessment of all types of risks			✓
22	Framework should be accessible			✓
23	Framework should be compatible with other risk assessments tools and methods			✓

6.4 PROPOSED RISK ASSESSMENT APPROACH

To design for an improved risk assessment approach, three concepts of a risk assessment framework were determined. These were the development of a guideline, a process diagram and a visual framework. Following the discussions made with the research group, such a guideline could be a long document that cannot be used in the everyday practices of healthcare staff. Some participants also criticised their many-paged risk assessment documents as requiring too much time, and healthcare staff tend not to read existing risk assessment policies and procedures. While a process diagram can show the risk assessment process from its inputs to outputs, it might not be detailed enough to highlight essential parts. Yet, a visual risk assessment framework can explain risk assessment

practice both by providing key points and demonstrating the risk assessment process with a sequence of activities.

The proposed risk assessment framework has been iteratively developed to improve its usefulness and usability. Since one of the requirements was to represent the proposed approach on an A4 size piece of paper, the initial risk assessment framework was designed to fit on an A4 sheet and also to meet all requirements. In so doing, the researcher was inspired by the *Inclusive Design Toolkit* (Waller et al. 2007) and *System Safety Assessment Toolkit* (Ward et al. 2017) that were designed at the Engineering Design Centre. After having discussions with the research team on the initial design of the proposed risk assessment framework, a need for an extension to the framework was revealed. It was not clear how to apply each step on the risk assessment model. At this point the researcher was influenced by the *IDEO Method Cards* (IDEO 2003). Although this approach would not meet with the requirement of fitting on an A4 size paper, compromises were needed to begin to address the varied requirements. So, explanation cards were added to the proposed risk assessment framework.

To document findings, a risk assessment form was designed by following the steps of the proposed risk assessment model. Then, the researcher conducted a case study and led regular group discussions to develop the proposed risk assessment framework further. At the same time, the researcher started conducting interviews with healthcare staff to evaluate the usability and usefulness of the proposed approach, and continuous improvements were made. This chapter provides the final version of the proposed risk assessment framework.

The major changes in the design of the proposed risk assessment framework are shown in Figure 6.2.

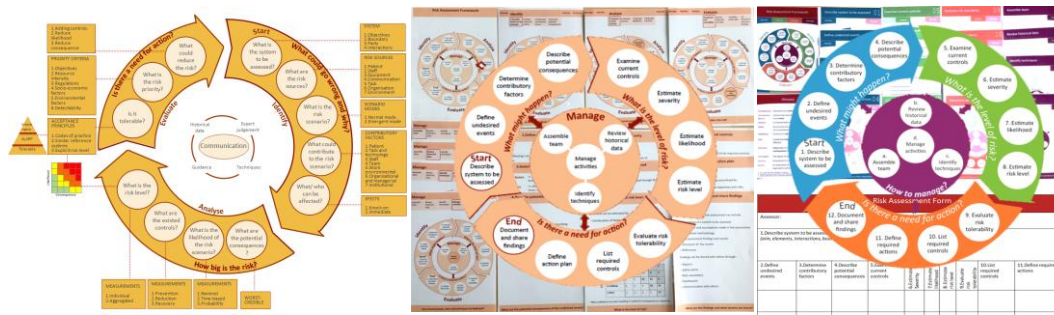


Figure 6.2 Initial versions of the risk assessment framework

In the earliest versions, the framework was drawn by providing questions in the circles of the risk assessment process cycle, and key prompts were listed in boxes outside of the cycle. While the framework explained the risk assessment process by addressing a set of questions, it was not always clear how to apply each step or activity that was described. Following the discussions made with the research group, questions turned to verb and noun formats, and the key prompts turned to explanation cards. Later on, a risk assessment form was added to allow the proposed risk assessment practice to be applied. In the final version, the framework consists of a risk assessment model, explanation cards and a risk assessment form.

The proposed risk assessment model is drawn in a circular shape to allow iteration in the risk assessment process and different colours are used to highlight different stages (Figure 6.3).



Figure 6.3 Proposed risk assessment model

It consists of identify, analyse, evaluate and manage phases, with four steps explained in each phase. Each step is explained with a card (Figure 6.4) to guide healthcare staff on its application by providing some prompts.



Figure 6.4 Risk assessment explanation cards

These cards can be used to assist healthcare staff in both risk assessment and training purposes since they provide a generic understanding of risk assessment (see Appendix 9 for the explanation cards). While the front of the cards represents which step is being explained, by asking the associated question, the reverse provides a number of prompts to support the application of the step.

6.4.1 IDENTIFY PHASE

Identify is the first phase of the risk assessment process, where the system is described, potential undesired events are defined, their contributory factors are determined and their potential consequences are identified. Therefore, this phase seeks to answer the question “*What might happen?*”

Figure 6.5 depicts a summary of the *identify* phase. Potential undesired events are defined by considering the system description. Following that, the factors contributing to these undesired events and their consequences are described. These steps are repeated until all potential events, their contributory factors, and their consequences are identified.

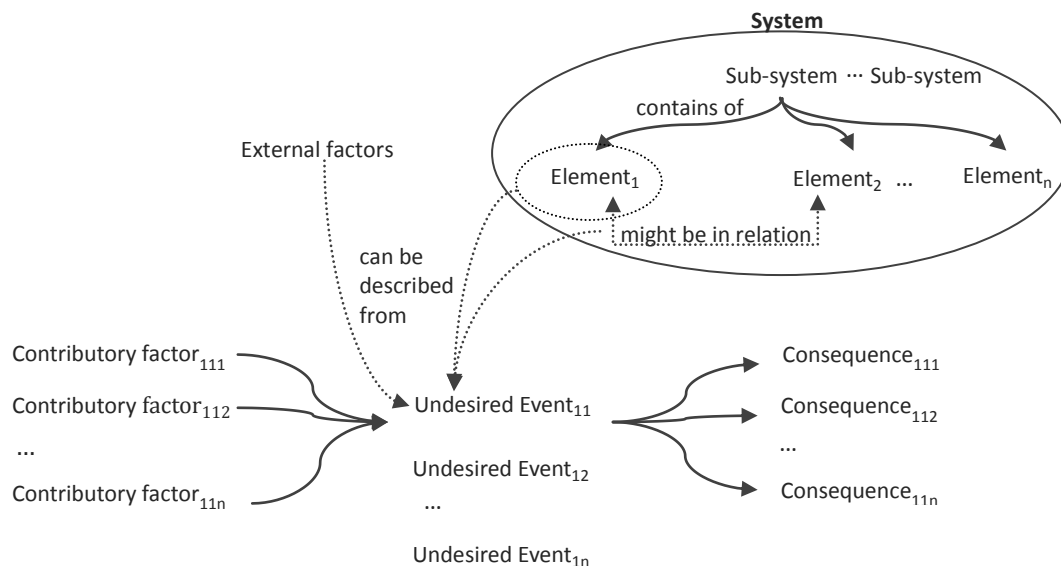


Figure 6.5 Summary of risk identification phase

To illustrate an example, a Mental Health Trust can be determined as a system and the process of an individual's admission is a sub-system, where entering an individual's details into the electronic system is one of its elements. When determining this element, there might be an undesired event of mistyping the individual's information due to the administrator being tired, the information being unreadable, the computer being broken, or the administrative staff being interrupted during the task of information entry. As a result, this might lead to mistreatment and distress as well as patient claims. So, risk can be defined, for instance, as a potential for mistyping the individual's details that result in error in treatment.

6.4.1.1 Describe system to be assessed

The system to be assessed needs to be described in order to identify all potential risks within the system. How well the system is described affects how many risks can be recognised. Therefore, this step aims to describe the system by addressing the question: *"What is being assessed and how does the system work?"*, by identifying the:

- assessment aim (*"What does the system aim to achieve?"*),
- system elements (*"What are the parts of the system?"*),
- interactions of the system elements (*"What is the relationship between the system elements?"*),
- system boundary (*"What is the scope of the system?"*),
- system context (*"What is around the system to be assessed?"*).

6.4.1.2 Define undesired events

Having built on the system description, potential undesired events are identified by responding to, *"What could go wrong?"* Undesired events are thus defined by considering the described system.

Undesired events can be categorised to help risk management. Organisations should set their own categorisation scheme based on their needs. Undesired

events can be categorised as: clinical practice (e.g. delayed discharge), organisation (e.g. bed shortage), health and safety (e.g. fire), and information (e.g. breach of confidentiality), for example.

6.4.1.3 Determine contributory factors

Since multiple factors can contribute to the occurrence of an undesired event, it is essential to understand the reason behind the undesired event. These factors can be viewed as risk sources. Thus, this step aims to determine all contributory factors of undesired events by asking, *“What could contribute to the occurrence of undesired events?”*

In Table 6.4, a classification scheme is presented to support consideration of all contributory factors.

Table 6.4 Contributory factors list

Contributory Factors	Examples
Patient factors	Clinical condition, physical factors, social factors and psychological factors
Staff factors	Physical factors, psychological factors, social factors, cognitive factors, and skills and knowledge
Task factors	Unfamiliar task, difficult task and monotonous task
Communication factors	Poor verbal and written communication, lack of feedback between all stakeholders, and lack of information provided
Equipment factors	Poor design, equipment not working, and inadequate maintenance
Control actions	No actions, unsafe actions, actions too late, too early or out of sequence and actions stopped too soon or applied too long
Organisational factors	Organisational structure, policies, procedures and protocols, staffing/workload factors, training and safety culture
Environmental factors	Physical environment, external environment (e.g. external authorities and suppliers)

Consideration of all the contributory factors not only guides assessors to identify all those factors leading to the undesired events, it also helps the assessor determine the controls required to prevent undesired events. However, it must be noted that not all undesired events can be prevented.

6.4.1.4 Describe potential consequences

Consequences are the outcomes of the potential undesired events. This step describes all potential consequences by addressing the question: *“What are the potential consequences of the undesired events?”*

A single event might have multiple consequences. These consequences can be categorised based on the impacts on:

- people (e.g. harm),
- organisation (e.g. reputation),
- environment (e.g. waste disposal).

For instance, patient falls might lead to patient harm, formal complaints and low staff morale. In addition, the effects of these consequences can be:

- immediate (e.g. if an old patient falls, this could result in hip fracture)
- knock-on (e.g. hip fracture could lead to death in the long term)

6.4.2 ANALYSE PHASE

Having built on the identify phase, risks are analysed to determine their level of risk. This phase involves examining current controls, estimating severity of the consequence, estimating likelihood of occurrence and estimating risk level. Therefore, this step aims to address the question: *“What is the level of risk?”*

To summarise the analysis phase, a diagram is shown in Figure 6.6.

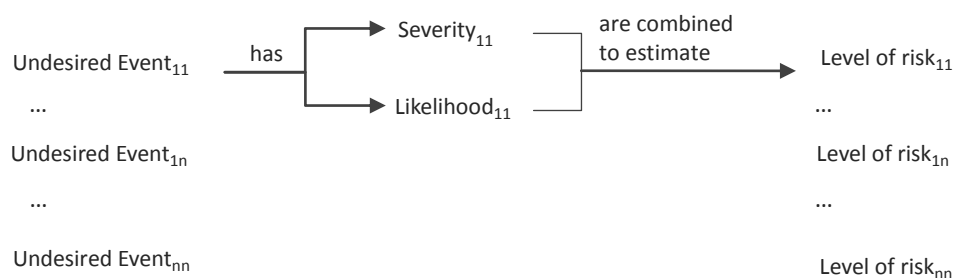


Figure 6.6 Summary of analyse phase

6.4.2.1 Examine current controls

In the system to be assessed, there might already be some controls in place, and these current controls should be examined to estimate the real risk level. Therefore, this step seeks to respond to the question: *“What are the current controls and how effective are they?”* These controls can be:

- to prevent undesired events,
- to detect undesired events,
- to reduce the severity of the consequences.

This is visualised as a system in Figure 6.7 by considering the undesired event, contributory factors and consequences.

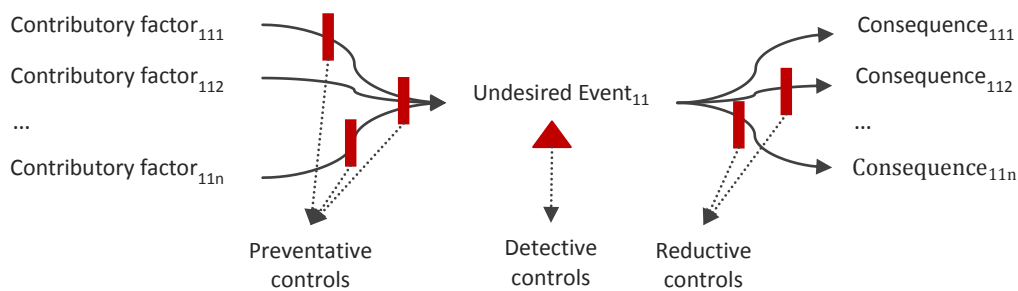


Figure 6.7 Potential controls in the system

Although it is essential to determine all existing controls, their effectiveness should also be measured by determining how well they perform in achieving their intended goal. The effectiveness of existing controls can be categorised as: effective, neutral and ineffective.

6.4.2.2 Estimate severity

The consequences of an undesired event can have varying degrees of severity. Severity determines the significance of the consequences. Therefore, this aims to address the question *“How severe are the described risks?”*

The severity of a risk can be estimated before considering the existing controls, by considering existing controls and after the implementation of the additional required controls. While estimating all would help management to understand the inherent, current and residual risks, it is the current severity of a consequence which needs to be determined to reveal the real level of a risk. This is estimated by identifying existing controls in the system and assessing their effectiveness.

Severity can be categorised with a nominal descriptor as well as with descriptions provided for each consequence domain. For practical reasons, a score of 1 to 5 is assigned to each descriptor and description. For instance, Table 6.5 provides an example of such guidance provided for the consideration of harm.

Table 6.5 Severity rating guidance by considering harm

Severity Score	Nominal Descriptor	Explanation (harm)
1	Negligible	Minimal injury requiring no/minimal intervention or treatment
2	Minor	Minor injury or illness requiring minor intervention
3	Moderate	Moderate injury requiring professional intervention
4	Major	Major injury leading to long term incapacity/disability
5	Catastrophic	Death or multiple permanent injuries or irreversible health effects

Since a risk might result in different degree of severity in the same consequence domain, a worst-credible strategy can be applied. For instance, patient falls might result in different degrees of harm such as minor injury, hip fracture or death. As patient falls leading to death would be a really rare case, hip fracture can be determined as a reasonably worst-credible case.

6.4.2.3 Estimate Likelihood

The likelihood of occurrence of a risk is evaluated when estimating the level of risk. This step seeks to respond to the question: *“What is the likelihood of occurrence of the consequences?”*

Likelihood can be categorised in three ways: with a nominal descriptor, time-based descriptions and probabilistic descriptions. Again, a score of 1 to 5 is assigned for each descriptor and description. For instance, Table 6.6 demonstrates an example for all likelihood categorisation schemes based on the existing guidance provided by the report of “*A risk matrix for risk managers*” (NPSA 2008).

Table 6.6 Likelihood rating guidance

Likelihood Score	Nominal Descriptor	Time-based Descriptions	Probability Descriptions
1	Rare	Not expected to occur for years	<0.1 %
2	Unlikely	At least annually	0.1- 1%
3	Possible	At least monthly	1-10 %
4	Likely	At least weekly	10-50 %
5	Almost certain	At least daily	>50 %

Probability descriptions can be used for one-off projects whereas time-based descriptions can be used for continuous operations.

6.4.2.4 Estimate risk level

Risk level is estimated by combining the severity and the likelihood of a risk to support risk based decisions. Therefore, this step seeks to respond to “*What is the level of risk?*”

Risk level is estimated by multiplying the severity and likelihood ratings. Since scores are assigned to each descriptor, risk level is estimated by multiplying the severity and likelihood scores. Risk levels can be categorised as low (L), medium (M) and high (H) risks. Risk matrices are used as shown in Figure 4.1 to present the risk level as well as to support the evaluation of the risks.

6.4.3 EVALUATE PHASE

This step uses the findings from the analyse phase to compare them with the risk criteria to decide whether or not the risk is tolerable and whether there is any

need to take action. Thus, this phase aims to address “*Is there any need for action?*” To do so, the tolerability of a risk is evaluated, required controls are listed, required actions are defined and findings of the assessment are documented as well as shared.

6.4.3.1 Evaluate risk tolerability

Since risks operate at different levels, some are more or less tolerable than others. Therefore, this step seeks to answer the question: “*How tolerable is the risk?*”.

Decisions on the tolerability of a risk can be taken by considering the risk in combination with the following factors:

- explicit risk level
- written rules
- potential benefits of taking the risk.

The explicit level of risk can give some insights into the tolerability of the risk. Low risks, which are assigned to green coloured cells as in Figure 4.1, are often found to be *generally tolerable*. Medium risks, assigned to orange coloured cells, are *generally undesirable* and red ones, assigned to red coloured cells, are *generally intolerable*.

6.4.3.2 List required controls

Putting additional controls into the system to be assessed can modify risks. To do so, first all the controls required should be listed. Therefore; this step seeks to address “*What new controls are required to modify the risk?*” These controls can be listed by considering:

- ineffective existing controls
- contributory factors
- controls to prevent undesired events

- controls to detect undesired events
- controls to reduce the severity of consequences.

However, it should be also noted that new controls might raise new risks in the system.

6.4.3.3 Define required actions

To put such controls in place, actions are needed. Therefore, this step seeks to address the question *“What actions are required to implement the new controls?”*

This step aims to define:

- a list of required actions
- action prioritisation
- management responsibility for these actions
- review frequency of the risks.

Required actions are determined through taking into consideration the list of required controls. The recommended actions should be *Specific* (e.g. what, why and how), *Measurable*, *Achievable*, *Realistic* and *Timely* (SMART). Actions can be prioritised by considering the criticality of the risk(s) to be modified (e.g. level of risk, the rapidity with which the risk will manifest itself and its detectability), organisational objectives, legal requirements, and required resources. Management responsibility is assigned by considering the estimated level of risk, and if the assigned staff do not resolve a risk, it can be escalated to a higher managerial level.

To check whether or not the defined action plan is in place, regular reviews can be organised and additional reviews can be arranged if necessary.

6.4.3.4 Document and share findings

All assessed risks should be documented to review risks and share findings. This step, therefore, seeks to address *“What are the findings and what lessons are learnt?”*

Documented risks can be changed over time, and, therefore, they should be reviewed. However, they should be documented first. A risk assessment document should cover the following information:

- description of the system to be assessed
- limitations and assumptions made in the assessment
- assessment methodology
- risk assessment findings and results
- discussions of the results
- references.

Assessment findings should be shared to make sure all lessons are learnt by all relevant stakeholders. The assessor or the assessment team should share findings with all relevant staff. Having implemented the required actions, updated feedback is provided to the assessor or the assessment team as well as all relevant staff. Additionally, feedback can be also given to the relevant stakeholders. Following this, the whole organisation can be informed about the significant findings of the assessment. This can be achieved by establishing reports or risk newsletters as well as by informing people during meetings.

6.4.4 MANAGE PHASE

This phase involves management of all steps to conduct effective risk assessment by seeking to answer the question *“How to manage?”*. In so doing, a team should be assembled, historical data should be reviewed, techniques should be identified to conduct assessment and all activities related to these should be managed at all stages of the risk assessment process.

6.4.4.1 Assemble team

Effective risk assessment practice requires the involvement of a multidisciplinary team. This step aims to maintain and sustain appropriate people in the team by seeking to address *“Who should be in the assessment team?”* To assemble a team, it is recommended to have at least:

- a facilitator with experience in risk assessment,
- a multidisciplinary group of experts in the system to be assessed.

A properly selected team can help identify more risks objectively. Selection of the team members would depend on the assessment context. It is desirable to have an external team member, who is not directly involved in the system, in the assessment team to prevent cognitive bias.

6.4.4.2 Review historical data

Historical data is useful to predict future events that follow past trends. To benefit from the historical data, this step aims to respond to, *“What can be learnt from historical data?”*

Historical data can be obtained from incident reports, risk registers, quality and performance reports, organisational or national safety alerts, audit reports and national or international reports.

However, it should be noted that the healthcare system is a dynamic system. Thus, not all events follow the same trends, and risks might change over time. That is why additional techniques are employed to predict future events.

6.4.4.3 Identify techniques

There are a large number of risk assessment techniques available in the literature. Risk assessment techniques are used to reveal known and unforeseen risks and to carry out effective assessments. Therefore, this step aims to address *“Which techniques should be used?”*

Different techniques can be used in different circumstances. System diagrams can be used to describe systems. Peer review and team discussions can be used to make better judgements. Brainstorming, structured what-if and Delphi techniques can be used to identify large sets of risks. Bow-tie (or barrier) analysis can be used to display the pathway of an event from its contributory factors to consequences as well as to examine current controls. Furthermore, more structured risk assessment techniques, such as FMEA or HAZOP, can be used to identify the ways failures occur and the ways they could be treated.

Additionally, risk assessment forms can be used to conduct risk assessments. The risk assessment form that was designed for the application of the risk assessment model developed here, and which also documents findings, is given in Figure 6.8.

Risk Assessment Form									
Assessor:		Ward/Department:		Date assessed:		Assessment no:			
1. Describe system to be assessed (aim, elements, interactions, boundary, context)									
2. Define undesired events	3. Determine contributory factors	4. Describe potential consequences	5. Examine current controls	6. Estimate Severity	7. Estimate likelihood	8. Estimate risk level	9. Evaluate risk tolerability	10. List required controls	11. Define required actions

Figure 6.8 Proposed risk assessment form

6.4.4.4 Manage activities

A large number of activities can take place when conducting a risk assessment. Each risk assessment step is tied to another one, and all steps are iteratively repeated until all risks are assessed. Therefore, it is necessary to manage all activities and to deploy the best use of people, data and techniques throughout risk assessment.

This step addresses the question: “How should people, data and techniques be deployed throughout risk assessment?” Thus, it is essential to:

- communicate with all stakeholders of the assessment at all times
- review the assessed risks on a regular basis as well as when there is a change in the system
- iterate through all steps of the risk assessment framework
- tailor the framework to the assessment needs.

Communication with the assessment team and other relevant stakeholders is key to good risk assessment. Building strong communication between relevant stakeholders not only helps towards effective risk assessment; it also facilitates the sharing of lessons learnt from the risk assessment.

All assessed risks should be reviewed on a regular basis as well as when there is a change in the system or it is made otherwise necessary. The review frequency can be set by considering the tolerability of the risks. For instance, tolerable risks can be reviewed annually; undesirable risks quarterly; and intolerable risks monthly.

Risk assessment is an iterative process. Iterations can be between different steps or the entire risk assessment process may need iteration.

While a number of prompts have already been provided in order to conduct an effective risk assessment, the framework should be tailored to the needs of the risk assessment.

6.5 DISCUSSION

The proposed risk assessment framework aims to support healthcare staff in carrying out better risk assessment practice. BSI (2009) states, *“The success of risk management will depend on the effectiveness of the management framework providing the foundations and arrangements that will embed it throughout the organisation at all levels.”* Designing a framework has also been found to be useful by other researchers in supporting healthcare staff with a variety of patient safety topics (Hinrichs 2009; Simsekler 2014; Card 2013). For instance,

Simsekler (2014) designed a risk identification framework to represent the inputs and outputs of a risk identification process and found it useful in recognising more risks; and Card (2013) developed a risk control tool to generate stronger risk controls. This research, similarly, proposes a risk assessment framework by building on both of these researchers' studies.

Turning to the requirements listed in Table 6.3, the proposed framework was designed to meet all requirements. However, there were two requirements that could not be met: *"The improved approach should fit to an A4 sheet"* and *"Uncertainties should be determined when assessing risks"*. While the early versions of the risk assessment framework aimed to fit on an A4 page, it was difficult to address the challenges discussed in this thesis and also meet this requirement. The framework aims to minimise uncertainties by encouraging the consideration of detectability and team involvement. However, it is not designed to measure uncertainty. This was due to the fact that most of the risks identify to existing issues and even consideration of two dimensions (likelihood and consequence) was problematic. Also, it could have increased the time needed to conduct the risk assessment, and minimising the time taken was also another requirement. This was also a requirement that can arguably be determined as met. There are different types of risk assessments, as explained in Figure 5.9, and not all of them require all steps to be completed. Thus, the framework allows flexibility, but encourages the completion of all steps when necessary. While it may still be thought to be time consuming by healthcare staff, the appropriate application of the proposed framework is believed to save time overall by minimising harm and loss that might occur in the future.

Yet, it must be mentioned that there could be other ways of improving current risk assessment practice, and so different ways of designing an improved risk assessment practice need to be considered. This study focuses solely on what is believed to be possible to change and to implement, but still the framework could have also been different in two ways: the terminology and the concept of risk assessment.

Regarding the terminology, the researcher aimed to limit using risk terms (e.g. hazard and risk) to ensure the simplicity of the framework. There has been ambiguity in the understanding of risk terms in even safety-critical industries (Aven 2012a; Aven 2010; Johansen and Rausand 2015). Not surprisingly, the findings of this research study also reveal that the use of risk terminology can be a problem. The simplification of these terms was also captured as a requirement. Thus, the proposed framework aimed to use ordinary language. In addition, an explanation card was provided just to describe all terms used in the proposed risk assessment framework.

Turning to the concept of risk assessment, the proposed framework used the term risk as a *“potential undesired event that has effect(s) on objectives”*. Although this definition is arguable and does not meet with the ISO definition as *“effect of uncertainty on objectives”* (BSI 2009), the evidence so far shows that risks are often used to refer to a current problem. Thus, this research followed a traditional approach by considering risk as a potential undesired event.

Additionally, consideration of the Safety II approach might make a significant contribution to the current risk assessment practice. Hollnagel *et al.* (2015) published a white paper on the need to move from Safety I to Safety II in healthcare. Therefore, the proposed framework could have been designed to consider *“What does the system aim to achieve?”*, *“What are the functions or elements in the system, and how do they operate?”*, *“How do things go right?”* and *“Which actions should we take and in what order of priority to make sure things go right?”* However, this approach has not yet been widely used and there are a number of criticisms regarding the usability and adoptability of Safety II (Carthey 2013; Larouzée and Guarnieri 2015; Roelen et al. 2011). In fact, there is even little evidence to show that risk assessment, from the Safety I perspective, could have been sufficiently applied in healthcare (Card et al. 2012b; Dul et al. 2012; Gray and Cohen 2012; Vincent et al. 2013; Ward et al. 2010). Thus, the framework is predominantly built on the Safety I approach by providing a number of prompts that were generated from the limitations of the current risk assessment practice and the requirements captured to improve current practice.

6.6 SUMMARY

This chapter has presented the risk assessment approach developed in this research. It is an approach which has taken into account all the requirements of as well as challenges in the current risk assessment practice. The proposed practice is represented with a risk assessment framework. The framework aims to support healthcare staff in risk assessment, and it involves a risk assessment model, explanation cards and an assessment form. The risk assessment model consists of 12 main steps, with 4 steps to be considered at each of these 12 steps. Each step is explained with an explanation card to provide a better understanding of how each step can be applied; and the risk assessment form is provided to support the application of risk assessment practice and to document findings.

The proposed risk assessment framework was developed after evaluating the general principles behind different risk assessment guidelines, as well as by considering the ways in which current risk assessment practice in hospitals needs improving. For instance, this framework encourages a consideration of the system to be assessed not only from its elements, but also their interactions. Additionally, it determines contributory factors by also determining control actions, and it encourages the determination of multiple factors when making risk-based decisions rather than solely relying on risk matrices. Since the framework clarifies the fundamentals of risk assessment practice, adopts elements of best practice from safety-critical industries, and is based directly on research findings regarding current healthcare risk assessment practice, it is expected to provide adequate support to healthcare staff on understanding and conducting risk assessment.

The next chapter evaluates the proposed risk assessment framework.

CHAPTER 7

EVALUATION OF PROPOSED RISK ASSESSMENT APPROACH

7.1 INTRODUCTION TO THE EVALUATION OF PROPOSED APPROACH

The previous chapter proposed a risk assessment framework to support healthcare staff during risk assessment. This chapter evaluates this framework to determine potential improvements as well as to test its usefulness, perceived usability and expected value through conducting a case study, interviews and a questionnaire. In so doing, this chapter aims to address the research question: *“What views do healthcare staff have on the proposed risk assessment practice?”*

7.2 METHODS

As mentioned earlier in Section 6.2, this chapter investigates the right-hand-side of the Vee developmental model (Figure 6.1) utilised in designing the proposed risk assessment framework. Evaluation of the framework was conducted through group discussions, a case study, interviews and a questionnaire. These methods

were particularly selected to minimise the time required to be involved and to maximise the number of participants involved.

A case study was undertaken by the researcher to test the proposed practice and to show an example to participants of its application. A scenario was developed through reviewing the literature to provide a real-life example, and the proposed framework was used to conduct the risk assessment. The scenario for the case study was as follows:

In a hospital setting, a neuro-rehabilitation unit will be moved from an old building to a new building, and the standards of the patient rooms will be changed. Since there is a change in the system, a risk assessment will be conducted to assess risks in the new neuro-rehabilitation unit before the move occurs. As part of this, a risk assessment will be conducted to assess all risks in relation to the patient's accommodation in a single-bed patient room.

The case study was first discussed with three members of the research group and, in turn, necessary adjustments were made to the design of the case study as well as for the framework. The completed case study was then shared with interviewees to represent an example of the potential use of the proposed approach.

Informal interviews were arranged by sending invitation emails to potential participants. In addition to the use of existing contacts, the researcher identified potential participants through reviewing profiles of NHS staff on LinkedIn. The selection of these participants was based on their profile information to ensure they had sufficient experience of risk assessment. After filtering their profiles based on their job titles, a number of participants were selected and sent the invitation email, and the interview time was arranged with those participants who were willing to participate. Prior to the interviews, the risk assessment framework and an evaluation form were sent to the participants, and participants were informed about the research study and interview schedule. Interviews were

conducted face-to-face or by telephone to reach more participants from different geographical regions in England.

Interviews consisted of two parts. In the first part, the researcher provided the risk assessment framework explanation cards to the participants, and explained the proposed approach using the case study as an example. The participants were allowed to interact at any point. In the second part, discussions were held with the participants regarding their feedback on the framework.

Interview participants then completed a questionnaire following discussions (see Table 7.2). If the interview was a telephone interview, participants delivered their questionnaire responses by email. The questionnaire consisted of three parts. Firstly, there were four questions that were designed to understand the characteristics of the respondents (e.g. job title, years of experience and frequency of involvement in a risk assessment). Secondly, seventeen predetermined statements were provided to participants to decide the level of their agreement or rejection of the given statement through the use of a Likert scale (i.e. strongly agree, agree, neutral, disagree and strongly disagree). Among these seventeen statements, eight were about the usefulness of the proposed approach, three were about usability and six were about expected value. In the last part of the questionnaire, participants were encouraged to respond to three open-ended questions to help the researcher improve the current version of the proposed approach.

7.3 RESULTS FROM THE EVALUATION

The case study was used to test the risk assessment framework as well as to test to provide an example of its potential application. Different versions of the proposed risk assessment framework were used to test how each step functions with the predetermined risk assessment scenario. For instance, the first version identified risk sources first and then risk scenarios. Subsequently, this was reversed, with the identification of undesired events coming first and then

contributory factors, which could then be considered as risk sources. The difficulty of identifying risk sources was also observed in current practice. Yet, it was found to be easier to identify a potential undesired event and then consider all contributory factors that would give rise to it.

To test the proposed risk assessment framework, the researcher conducted a risk assessment by considering the given scenario through completing the designed risk assessment form in line with following prompts. Figure 7.1 partially demonstrates the completed risk assessment form for the given scenario (see Appendix 10 for the complete risk assessment form).

Risk Assessment Form (Example)										
Assessor: G K Kaya		Ward/Department: Risk Management/ EDC			Date assessed: 01/08/17			Assessment no: 001		
<p>1. Describe system to be assessed (aim, elements, interactions, boundary, context)</p> <p>Aim: To identify all risks in relation to the patient's accommodation in the new single-bed patient rooms</p> <p>Elements: Physical elements include patient bed, over-bed table, bedside table, 2 chairs, wardrobe, TV, sink, light, bin, hand hygiene dispensing, floor, nurse call button and sphygmomanometer; stakeholders include patient, nurse, physician, doctor, physiotherapist, dietitian, speech and language therapist, hospital manager, suppliers and so on; activities involve patient transportation from bed to wheelchair, patients being checked, patient being slept and so on.</p> <p>Interactions: Communication between stakeholders and activities</p> <p>Boundary: Consideration of patient safety related risks in the new single-bed patient rooms</p> <p>Context: Patient's treatment delivery process, national standards for a single-bed patient rooms and hospitals care delivery process.</p>										
2. Define undesired events	3. Determine contributory factors	4. Describe potential consequences	5. Examine current controls	6. Estimate Severity	7. Estimate likelihood	8. Estimate risk level	9. Evaluate risk tolerability	10. List required controls	11. Define required actions	
Patient falls off the bed	Patient's old age, weight and clinical conditions, inadequate bed rails, room size	1.1 Minor cuts 1.2 Grazes 1.3 Hip fractures 1.4 Death 1.5 Patient Loss of confidence 1.6 Formal complaint	-Soft floor surface (neutral) -Nurse checking patient (neutral) -Nurse call button (neutral)	1 2 4 5 3	3 3 1 1 3	3 Low 6 Low 4 Low 5 Medium 9 Medium	Tolerable Tolerable Tolerable Undesirable Undesirable	Replacement of the bed rails Decreasing the height of bed for vulnerable patients	Management should open a request to purchase bed rails; review after 6 months Nurses should adjust the height of the bed when necessary	
Patient suicide	Patients psychological condition, unsafe actions and untrained staff	2.1 Patient's serious injury 2.2 Patient's death 2.3 Patient claims from relatives	-Building friendly communication with (neutral) -Suicide risk assessment (effective)	4 5 3 2	1 1 1 1	1 Low 5 Medium 3 Low 2 Low	*Undesirable *Intolerable Tolerable Tolerable	Training staff on communication Removing sharp items if patient is assigned to have a risk of suicide	Management and training team should add communication topic into their induction training course; review after 6 months Nursing staff should assess the risk of suicide for each patient, and take appropriate actions immediately	
Fire in the room	Physical environment, smoking detector, building insulation material, lack of staff training, fire extinguisher	3.1 Multiple deaths 3.2 Multiple serious injuries	-Fire safety training during inductions (effective) -Fire safety regulations (neutral)	5 5	1 1	5 Medium 5 Medium	*Intolerable *Intolerable	Maintenance for the smoking detectors and alarm system Checking the expiry dates for the fire extinguisher Having fire evacuation drills	Management should arrange a contractor to have the relevant checks from time to time; review after a month Health and safety officers should test fire alarm weekly Risk management and health and safety officers should organise a fire evacuation drill each year	

Figure 7.1 A completed risk assessment form

The interview and questionnaire were conducted to evaluate the experience of potential users of the proposed risk assessment framework. There were ten participants that were involved in both the interview and questionnaire. While two of these participants (F6 and T10) were previously involved in other studies conducted in this research, eight of the interviewees were new to it. The characteristics of the participants are given in Table 7.1.

Table 7.1 Characteristics of participants for evaluation questionnaire

Identifier	Interview Type	Interview Duration	Type of Trust	Position	Years of Experience in NHS	Frequency of Involvement in a Risk Assessment
F6	Face-to-face	120 mins	Acute teaching	An anaesthetist	9	Rarely
T10	Face-to-face	120 mins	Acute specialist	Risk manager	30	Daily
F7	Face-to-face	90 mins	Acute teaching	Clinical scientist	15	1 per week
F8	Face-to-face	83 mins	Acute specialist	Head of risk management	15	Daily
F9	Face-to-face	83 mins	Acute specialist	Head of governance and improvement	8	Rarely
T11	Telephone	29 mins	Other	Consultant in risk leadership	25	A few times in a week
T12	Telephone	68 mins	Acute	Quality and safety manager	10	Daily
F10	Face-to-face	86 mins	Acute teaching	Clinical engineer	15	1 per 2 months
F11	Face-to-face	82 mins	Acute teaching	Corporate risk/ project manager	8	Weekly
T13	Telephone	28 mins	Other	Clinical director	35	At least monthly

The average completion time for each interview was approximately 79 minutes, and the average number of years' experience in NHS for a participant was 17. Observations from the interviews reveal that participants with risk management as part of their main responsibility or with the least experience of risk assessment tended to express greater interest than other participants. Yet, they were all interested in the research and the proposed framework.

Since the interviews were informal and not recorded, the main results were generated via the questionnaire. Following an interview, participants were requested to rate their acceptance or rejection of a list of given statements by selecting "*strongly agree*", "*agree*", "*neutral*", "*disagree*" or "*strongly disagree*". Table 7.2 shows 10 participants' responses to the listed statements.

Table 7.2 Results from the evaluation questionnaire

Statements	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Average
Usefulness						
I would be likely to identify more risks by using the RAF	2	3	4	1		3.6
I would be likely to analyse risks more effectively by using the RAF		9	1			3.9
I would be likely to better evaluate risks by using the RAF	1	8	1			4
I would be likely to assess risks more systematically by using the RAF	4	3	3			4.1
I found the RAF useful to guide me on risk assessment	3	6	1			4.2
Using the RAF could make me more confident about risk assessment	2	4	4			3.8
Using the RAF could improve current risk assessment practice	5	4	1			4.4
Using the RAF could make patients safer	3	2	4	1		3.7
Perceived usability						
I found the RAF clear and understandable	3	6	1			4.2
I found the RAF easy to use	2	7	1			4.1
I found the RAF easily compatible to our existing approach	2	7	1			4.1
Expected value						
The RAF improved my current knowledge on risk assessment	1	3	4	2		3.3
The RAF increased my awareness on risk assessment	1	1	6	2		3.1
The RAF could be beneficial to guide me on risk assessment	4	3	2	1		4
I can see the value in having the RAF	6	2	2			4.4
It is worth spending more time on risk assessment to use the RAF	3	4	3			4
Switching from the old approach to the RAF is essential	3	3	3		1	3.7

The average rating of the responses for each statement is shown in Table 7.2 and was calculated by assigning a score to each Likert scale category (i.e. strongly agree=5, agree=4, neutral=3, disagree=2 and strongly disagree=1) in order to aid numerical analysis.

In relation to usefulness, participants mostly agreed with the given statements. Participants agreed that the proposed risk assessment framework (RAF) would

improve their risk assessment practice with an average agreement rating of 4.4 out of 5. Regarding each step of the risk assessment, the RAF was found to be most helpful in terms of the risk evaluation step with an average agreement rating of 4. However, one participant claimed that it would not help her identify more risks or make patients safer at all. Despite this, all participants found it useful in guiding them on risk assessment with an average agreement rating of 4.2.

Although there were only three questions asked in relation to perceived usability, participants strongly agreed with the statements provided in this part. While only one participant was neutral, all other participants agreed or strongly agreed with these statements in relation to the RAF being clear and understandable, easy to use and easily compatible with their existing approach.

However, lower agreement ratings were received in relation to the expected value. Participants were more neutral on statements such as the RAF improving their current knowledge of risk assessment (with an average agreement rating of 3.3 out of 5) or increasing their awareness of risk assessment (with an average agreement rating of 3.1 out of 5). This could be due to participants' significant experience of risk assessment. However, they mostly agreed that the RAF could be beneficial in guiding them in assessing risk (with an average agreement rating of 4) or they agreed that they could see the value in having the RAF (with an average agreement rating of 4.4). This, however, was not enough for them to strongly agree that they would switch from the old approach to the RAF, which was still reasonably agreed with an average agreement rating of 3.7.

In addition to these results, participants were given the opportunity to make brief comments on three open-ended questions to improve current versions. When it was asked *"What is familiar and what is new about the RAF?"*, they all provided a brief explanation. For instance, T13 stated, *"The general framework is familiar. However, it builds in a more robust and comprehensive approach to risk assessment and risk control"*. F10 recognised that the iterative cycle reflects the design process toolkit and highlighted the reduced jargon and technical terms. Similarly, T11 pointed out that *"the methodology is presented in much more user-*

friendly terms than by experts such as ISO 31000 and the Health and Safety Executive”.

T12 highlighted that the inclusion of the contributory factors was the part she liked most. She also added *“I would see my primary use of the RAF as a training aid used during face to face training sessions, with staff then able to use the RAF as a post-training prompt to remind them of the steps they need to follow when carrying out a risk assessment.”*

Other respondents stated that the RAF is familiar to them in terms of its main steps, but they found the details to be new, systematic and helpful.

Participants were also asked *“What changes would you recommend to improve the RAF?”*, and seven of the participants responded to this question. T12 provided three recommendations: to have stronger linkages from contributory factors and controls/actions, to consider estimating the target risk score as well as the actual risk score, and to consider when to conduct a comprehensive risk assessment. T11 recommended having stronger links to objectives and to promote the framework for assessing opportunities as well as downside risks. T13 recommended the need for more explanation of what ‘system’ means.

T10 suggested providing additional cards to explain a number of risk assessment techniques to support assessment; whereas F9 found the card that lists techniques as too complicated and not very helpful. F8 recommended tailoring the cards to each target audience. Similarly, F7 recommended considering additional versions for specific uses as in medical device risk assessment, and F11 recommended having separate versions for clinical risk assessment and organisational risk assessment.

Finally, participants were given additional space to add further comments, and seven participants provided comments in this space. T10 stated that the RAF follows their new risk management training handbook closely, F9 found the framework to be well presented and simple to understand, and she stated that it could be used as a teaching aid. F7 found it very accessible and easy to follow.

F10 stated that she would like to implement it, F11 found it to be a useful tool, and F6 found the team approach necessary and found the RAF to be “*really good*”. T13 also appreciated the work by stating, “*I think this is an excellent framework that will help many people*”.

Although promising results were received from the evaluation of the RAF, it must be mentioned that these responses only reflect the opinions of the participants. However, given considering the participants’ experience in risk assessment, their feedback is of greater value than a higher number of responses received from participants having no experience in risk assessment.

7.4 DISCUSSION

The results provided an initial evaluation of the proposed risk assessment framework (RAF). Overall, the results were mainly promising and participants were satisfied with the usefulness of such a framework. They considered its use as a training package as well as a tool to assess risks. Yet, results were not that promising when it came to participants’ opinion on the essentiality of the replacement of their existing risk assessment approach with the proposed risk assessment framework. Furthermore, the RAF would not help healthcare practitioners overcome the barrier of *limited time availability* as the proposed practice encourages team involvement and follows a more detailed procedure than simply filling in a form, checklist or just relying on their professional judgement. However, it was noted that the proposed framework should be tailored depending on the needs. Considering the fact that risk assessment in hospitals is conducted in different ways as shown in Figure 5.9, not all risk assessments require such a comprehensive risk assessment. A comprehensive risk assessment can be considered when there is a change in the system (e.g. change in devices, people and process), a requirement (e.g. reports from external authorities), an on-going unresolved issue that raises risks, or potential for severe harm or loss (NPSA 2006; Hollnagel et al. 2013; NHS England 2015d).

Although the usefulness and perceived usability of the proposed risk assessment was evaluated in this chapter, the framework itself would make little impact on the system unless the assessment is taken a step further, and recommended actions are implemented. However, feedback indicates that it is thought that the RAF would improve current risk assessment. Indeed, good risk assessment would lead to better decisions made on risks, and subsequently better use of resources for modifying risks (DoD 1984). However, it must be noted that risk assessment is not a stand-alone activity, and it must be combined with other risk management activities.

While positive feedback was received from the evaluation of the proposed framework, the limitations of the evaluation process should be also mentioned. These were in relation to the selection of the participants and the design of the evaluation process. The researcher intentionally selected participants with experience in risk assessment to obtain more feedback on its improvement. However, participants with no experience in risk assessment might provide different responses. Although their responses would also contribute to this research, there could have been a possibility that they might not have known existing practice. Participants were selected from a range of professions including both clinical and non-clinical staff, and the framework was designed for all hospital staff that is involved in a risk assessment.

More importantly, the evaluation process has limits due to the methods used as well as methods not selected. The evaluation questionnaire was not designed to contain duplicating and reversing questions. Also, the questions were phrased positively, which might lead to various forms of bias including acquiescence bias and confirmation bias. Consequently, respondents might have biased selections made in favour of this research. Furthermore, the case study did not really allow participants to actually use the proposed risk assessment framework. Participants could have given more comments as well as more reliable responses in terms of the practicality of the proposed framework.

Alternatively, the evaluation process could have been designed differently to minimise any types of bias. A control study could have been used to evaluate the

proposed framework by involving two groups. First, both groups could have been given the same case study and expected to conduct a risk assessment by the same risk assessment guideline. This is to measure the ability of each group in conducting risk assessment. Later on, one group could have been provided an FMEA template with guidance and the second group could have been provided the proposed risk assessment framework to conduct a risk assessment on another the same case study. The findings of these two groups could have been then compared by considering the number of risks and contributory factors listed and the quality of control measures advised in order to demonstrate the real effect of the use of the proposed framework. However, this study was designed to only conduct an initial evaluation due to the limited accessibility and time availability of healthcare staff.

7.5 SUMMARY

The evaluation presented in this chapter of the risk assessment framework developed in this research provided valuable insights in terms of its usefulness, perceived usability and expected value as well as potential improvements. Participants agreed most that the RAF could improve current risk assessment, and they highlighted its value for use in training purposes.

Overall, the results indicate that the RAF would support healthcare staff in conducting risk assessments, and that its successful application could improve current risk assessment practice in hospitals.

CHAPTER 8

CONCLUSION

8.1 INTRODUCTION TO CONCLUSION

This chapter presents a brief response to each research question, discusses this study's contribution to the field of risk assessment research and the healthcare industry, and outlines a number of proposals for further work.

8.2 KEY FINDINGS AND CONTRIBUTIONS

This study set out to design a good risk assessment approach in hospitals to improve safety by investigating:

How can current risk assessment practice be improved to ensure safety in hospitals?

In order to address this research question, current risk assessment practice was investigated, the existing challenges were identified and a new approach was proposed by learning from prescribed good practice. In line with the main

research question, the following five research sub-questions were investigated throughout this research to respond to the main research question.

1. What is prescribed good practice in risk assessment?
2. How is current risk assessment performed in hospitals?
3. What are the problems with current risk assessment practice in hospitals?
4. How would good risk assessment practice be tailored to hospitals?
5. What views do healthcare staff have on the proposed risk assessment practice?

8.2.1 WHAT IS PRESCRIBED GOOD PRACTICE IN RISK ASSESSMENT?

This research reviewed a number of national and international safety and risk management standards to describe prescribed good risk assessment practice. Although good practice in other industries might not necessarily be the best practice in healthcare, key elements of good risk assessment practice were identified in Chapter 2 and Chapter 6 by considering their applicability to the hospital setting (see Table 6.1).

Overall, risk assessment practice involves three steps: risk identification, risk analysis and risk evaluation. The risk identification process involves taking into account risk sources, events, contributory factors and consequences. The risk analysis process includes the examination of existing controls, and the consideration of likelihood and impacts as well as other factors such as detectability, vulnerability and speed of onset. The risk evaluation process consists of determining risk tolerability and risk priority.

However, there are some particular details that matter for good risk assessment practice, including a clear system description, the identification of risks from their sources, having good communication between staff, the involvement of the right people, the use of the most appropriate techniques, the documentation of the assessment findings, and the identification of relevant actions following the risk

assessment. Indeed, good risk assessment practice requires multiple factors to be taken into account together, since risk assessment is not a stand-alone activity.

In the healthcare literature, there have been few studies published to provide guidelines on good risk assessment practice. While Simsekler (2014) conducted a research study that provides guidelines on risk identification and Card (2013) on risk control, there are a few studies conducted on risk assessment as a whole to describe good risk assessment practice. For instance, the National Patient Safety Agency has published two key reports, which are Risk Assessment Programme (NPSA 2006) and Healthcare Risk Assessment Made Easy (NPSA 2007), to guide healthcare staff on risk assessment. Even though the former report does provide a certain level of detail on how to conduct risk assessment, it advocates conducting risk assessment with cause-effect thinking, which supports the notion that risk assessment is built on traditional accident models. Additionally, the aforementioned report still does not offer much detail on how to analyse and evaluate risks. The latter report is also too generic and does not go into much detail on how to apply each step.

This research, however, modifies and combines the risk assessment standards provided from national and international organisations to describe good risk assessment practice. It treats risk assessment as something more than just a process. Thus, good risk assessment practice is described by also considering pre- and post-risk assessment activities. Moreover, this research describes good practice from the perspective of modern accident models where multiple factors can contribute to the occurrence of a potential undesired event, instead of simply examining causal relationships.

8.2.2 HOW IS CURRENT RISK ASSESSMENT PERFORMED IN HOSPITALS?

Current risk assessment practice in hospitals in NHS England was investigated in Chapters 4 and 5 using mixed methods, including document analysis, interviews,

questionnaires and a review of risk data. Analysis of all datasets reveals that there are three types of risk assessment (see Figure 5.9), which are:

- individual patient-based risk assessment, usually made using professional judgement or a specific risk assessment form, the findings from which are recorded in the patient records system;
- operational risk assessment, which can be initial, specialised or comprehensive, and which is made using professional judgement, specific risk assessment forms or risk assessment techniques, the findings from which are recorded in a risk register database;
- strategic risk assessment, often made through professional judgement, the findings being recorded in the Board Assurance Framework (BAF).

Different hospitals might assess risks slightly differently due to the risk matrix they used, the guidance provided, the assessors' professional judgement and hospital type. However, almost all of them use a similar process when assessing risks and predominantly use risk matrices when assessing operational risks.

In the healthcare literature, risk assessment often refers to specific assessments rather than to an overview of all risk assessment types. For example, numerous papers have been published on the assessment of venous thromboembolism (Wilson 2015), falls (Hendrich et al. 1995), and self-harm (O'Rourke and Bird 2001) related risks. There are also a few studies that have conducted comprehensive risk assessments (Bonfant et al. 2010; Broggi et al. 2013; Alba Mesa et al. 2015). However, none of them provide a holistic understanding of all risk assessment types performed in hospitals.

8.2.3 WHAT ARE THE PROBLEMS WITH CURRENT RISK ASSESSMENT PRACTICE IN HOSPITALS?

A number of problems were highlighted in Chapters 2, 4 and 5 in relation to the design of the risk assessment process (e.g. the risk matrix, the guidance provided and assessment steps), to its application (e.g. subjective judgement, lack of use of risk assessment techniques and the misuse of the risk terms) and to other factors

(e.g. limited time availability, poor risk-related communication and the perceived value of risk assessment) (see Table 5.12). The findings of this study reveal that most of the challenges stem from there being only a basic understanding of risk assessment.

This study provides evidence that supports and extends the existing knowledge of the challenges of current risk assessment practice. For instance, it was already claimed that a risk register system tends to be used as a bureaucratic data collection system (Illingworth 2015a). This study extends the existing knowledge that the risk register systems can be also used as a political tool to unfairly garner attention from higher managerial levels. Additionally, while risk scoring was claimed to be subjective (Card et al. 2013), this study provides evidence that healthcare staff may not use guidance to score risks, which increases the possibility of bias in risk scoring.

8.2.4 HOW WOULD GOOD RISK ASSESSMENT PRACTICE BE TAILORED TO HOSPITALS?

This research study reveals that there is indeed great potential to improve current risk assessment practice in hospitals. This research focused on designing a risk assessment framework by learning from prescribed good practice as well as current challenges. Good practice, in this research, refers to risk assessment practice that helps address the existing challenges and that is built on the prescribed good risk assessment of safety-critical industries. However, there could have been a variety of other ways to improve current risk assessment practice. For instance, improvements can be focused on organisational culture, regulations, or perhaps designing specific risk assessment techniques. Indeed, a combination of all these would have the greatest impact on the improvement of current risk assessment practice. However, this study focused solely on what is believed to be possible to change, and thus a new risk assessment framework was developed. To do so, requirements were captured from the literature review (Chapter 2) and the review of current risk assessment practice (Chapters 4 and 5)

to design the proposed risk assessment framework, following the Vee developmental model (see Table 6.3).

The proposed risk assessment framework aimed to support healthcare staff in better risk assessment practices. It consists of a risk assessment model, explanation cards with a number of key prompts to help implement the model, and a risk assessment form to allow its users to actually conduct a risk assessment following the proposed risk assessment model.

In hospitals, the risk assessment process is often described by a simple flow chart that does not provide sufficient detail on how to conduct risk assessment or by written statements that mostly focus on responsibilities rather than how to do. Even if some hospitals recommend implementation of a well respected risk assessment standard of ISO 31000, there are no details provided on how to transfer that knowledge into healthcare.

In the healthcare literature, there have been a number of studies published to encourage the healthcare industry to learn from safety-critical industries due to their risk assessment practice being considered as good or even better than the healthcare industry (Macrae 2008; Sujun et al. 2017; Vincent et al. 2014; The Health Foundation 2012; Ward et al. 2010). However, only Ward *et al.* (2010) conducts a study that tailors the prospective hazard analysis techniques for the use of healthcare staff by simplifying them and designing a toolkit.

This study; however, focuses on how to conduct risk assessment by tailoring the prescribed good risk assessment practice by also addressing the existing challenges.

8.2.5 WHAT VIEWS DO HEALTHCARE STAFF HAVE ON THE PROPOSED RISK ASSESSMENT PRACTICE?

Development and testing of the framework were conducted through many meetings between the three research group members. Following that the

proposed risk assessment framework was evaluated by conducting interviews and a questionnaire in Chapter 7.

The evaluation of the proposed risk assessment framework provided valuable insights in terms of its usefulness, perceived usability and expected value of. The participants' feedback indicated that it is useful in guiding people on risk assessment, and that it could improve current risk assessment practice. Additionally, participants highlighted its value as a training tool.

However, there was less agreement between participants regarding switching from the old approach to the proposed new approach. The proposed risk assessment requires spending more time on risk assessment, which is not desirable in healthcare. Thus, it is likely that participants would not easily switch from their old approach to the proposed risk assessment framework.

Furthermore, there was less agreement that the proposed risk assessment framework could make patients safer. Indeed, risk assessment is not a stand-alone activity as mentioned earlier. Therefore, it would be really difficult to predict any significant impact on patient safety without any follow up steps for the implementation of the recommended actions.

Turning to the main research question: *"How can current risk assessment practice be improved to ensure safety in hospitals?"*, the findings of this research study indicate that there are a range of ways to potentially improve current risk assessment practice. These could be through the development of a new risk assessment technique, the improvement of safety culture in hospitals, and the design of a range of risk assessment training courses as well as through the focus on specific issues such as the subjectivity of risk scoring and the clarification of risk terminology. For instance, Simsekler (2014) focused on providing an improved risk identification guide, and, similarly, Card (2013) focused on providing guidance on risk control. Additionally, Ward *et al.* (2010) designed a toolkit for the use of prospective hazard analysis techniques in the healthcare context.

This research, however, aimed to improve current risk assessment in hospitals by first providing a clear understanding of risk assessment practice as a whole, and then by developing a risk assessment framework to better support healthcare staff on conducting risk assessments.

8.2.6 CONTRIBUTIONS

This research provides important contributions to the current understanding of risk assessment practice in hospitals, and a new risk assessment framework. Actual risk assessment practice in hospitals is an area which appears to have been poorly described. In the literature, the risk assessment practice is only explained with a specific context as mentioned earlier, such as VTE, falls and self-harm. While some claims have been made related to actual risk assessment as in risk scoring being subjective (Card et al. 2013), and risk register systems being bureaucratic data collection (Illingworth 2015a), there are no studies conducted to provide evidence for the different types of risk assessment (e.g. individual patient-based and operational) by considering both the recommended and the actual practice. Indeed, this study revealed that the recommended and the actual practices are different.

This research aimed to fill this gap in understanding by investigating the current risk assessment process in hospitals in terms of both '*work as described*' and '*work as done*', and highlighting a number of problems in relation to its design and application. Although some of the challenges have been already identified, this study supports the findings of previous studies as well as extending the existing knowledge. For instance, while risk matrices are criticised in different industries in terms of their use and inherent limitations (Ale et al. 2015; Ball & Watt 2013; Baybutt 2015; Card et al. 2013; Cox 2008; Cox & Popken 2007; Duijm 2015; Smith et al. 2009; Vatanpour et al. 2015), there has been no study published so far to investigate applicability of such limitations in the healthcare context, other than a similar study with a limited scope (Card et al. 2013).

In doing so, this research has presented the big picture of current risk assessment practice in hospitals (Figure 5.9), and developed a framework to support healthcare staff in good risk assessment practice, a framework, which has undergone an initial evaluation and been found to be useful in guiding healthcare staff in risk assessment.

8.3 LIMITATIONS AND FURTHER WORK

A number of limitations have been encountered in this research, which led to the consideration of further work. Limitations are in relation to access to resources, literature review, sampling, the generalisability of the research and the evaluation of the proposed risk assessment framework.

It was difficult to access resources from hospitals and to obtain ethical approvals. The researcher obtained two approvals to access data and people, a letter of access and Health Research Authority (HRA) approval. A letter of access was obtained through the application of a research passport to the Cambridge University Hospitals NHS Foundation Trust. Further permissions were also gained from the Trust's risk manager to access the Trust's risk management system. HRA approval was obtained to conduct the research in multiple other NHS organisations in England. It took a considerable amount of time to obtain approvals.

This research conducted a narrative review in Chapter 2 instead of a systematic review. While narrative review mostly relies on the experience of the researcher to include studies, systematic reviews include studies based on the predefined selection criteria (Pae 2015). As a result, the literature review for risk assessment in Chapter 2 could be subjective and, therefore, biased by the researcher's selections. However, this was aimed to be minimised by conducting group discussions with the members of the research group, who have expertise in safety and risk assessment. Further work could be done by conducting a systematic review of the applications of the risk assessment practice in hospitals

by the use of same databases. This could have provided more detailed information on the application areas of risk assessment in hospitals, and reliable evidence for the real effect of the use of risk assessment on the care delivered.

Additionally, sampling was found to be another limitation of this research study. This research used purposive sampling, where sampling is non-probabilistic and based on a set of selective criteria (Holloway and Wheeler 2010), by only conducting interviews with healthcare staff having experience in risk assessment. This was due to the fact that many healthcare staff might not have adequate knowledge of risk assessment and it was difficult to involve healthcare staff in this research study, due to their limited time availability and unwillingness to participate in such a study. Since purposive sampling might lead to bias, mixed methods were used to minimise bias in this research study including document analysis, interviews, questionnaires and risk management data analysis. However, the selected sampling strategy also ignored other key stakeholders within the risk assessment practice such as regulators and patients. While the hospital staff are the primary participants of the risk assessment practice, regulators have a significant influence on the way they conduct risk assessments, and patients might help healthcare staff understand the system to be assessed from patients' perspectives as well as by recognising their needs. While it is arguable to what extent patients should be involved in risk assessment, they can have a significant contribution to the risk assessment. Further studies can, therefore, be conducted by understanding the roles of regulators and patients in the current risk assessment practice.

Using purposive sampling could lead to criticism of the generalisability of the research. Although some hospitals might conduct risk assessment slightly differently in detail, the review of the risk assessment policies and procedures in Chapter 4 revealed that the main process of risk assessment is similar in all hospitals. Despite this, participants' views on risk assessment can be different even in the same hospital. However, the proposed risk assessment framework can still be generalisable since it provides support for good risk assessment practice in hospitals.

Evaluation of the proposed risk assessment is also limited. Firstly, the evaluation questionnaire was not designed to provide duplicating and reversing questions to establish the reliability of the responses. Secondly, participants' views on the proposed risk assessment framework could have been biased since they evaluated the framework based on the explanations rather than on their experience of using it. Ideally, the actual impact of the proposed framework would be assessed in a real-life setting, but practically it is difficult to convince healthcare staff to use such a framework in this setting. However, as mentioned earlier in Section 7.4, a further evaluation could be conducted through a control study by having two groups. First, both groups could be provided a first case study and expected to conduct risk assessment by the use of their hospital's risk assessment documents. Later on, one group could be provided an FMEA template with guidance and the second group could be provided the proposed risk assessment framework to conduct risk assessment on a second case study. The findings of these two groups could then be compared to demonstrate the real effect of the use of the proposed framework.

Additionally, the proposed framework could be further evaluated in a wider setting through involving risk assessment experts in other industries and healthcare professionals as well as external authorities to learn from their experiences. Lastly, a computer-based version of the proposed risk assessment framework could be designed to improve the accessibility of the proposed framework.

In conclusion, this research sheds light on the existing risk assessment practice in hospitals in England by revealing the described and the actual practice, and it provides a useful framework for supporting healthcare staff to assess both clinical and non-clinical risks.

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APPENDIX 1: A LIST OF STANDARDS AND GUIDELINES

Standard/ Guideline	Title
AS/NZS 4360: 1999	Risk management
BS 6079-3: 2000	Project management- part 3: guide to the management of business related project risk
BS 8444-3: 1996	Risk management- part 3: guide to risk analysis of technological systems, London:
BS 8800: 2004	Occupational health and safety management systems- guide
BS EN 15224: 2011	Health care services- quality management systems- requirements based on EN ISO 9001:2008
BS EN 31010:2010	Risk management: risk assessment techniques
BS EN 60812: 2006	Analysis techniques for system reliability: procedure for Failure Mode and Effects Analysis (FMEA)
BS EN 62198: 2014	Managing risk in projects- application guidelines
BS EN ISO 14971: 2012	Medical devices- application of risk management to medical devices
BS EN ISO 17776: 2002	Petroleum and natural gas industries- offshore production installations- guidelines on tools and techniques for hazard identification and risk assessment
BS ISO 31000: 2009	Risk management: principles and guidelines
BS ISO 31100: 2011	Risk management- code of practice and guidance for the implementation of BS ISO 31000,
BS ISO/IEC 16085: 2004	Information technology- software life cycle processes- risk management
CAP 760: 2010	Guidance on the conduct of hazard identification, risk assessment and the production of safety cases
COSO: 2004	Enterprise risk management- integrated framework
COSO: 2012	Risks assessment in practice

HM Government: 1974	Health and Safety at Work Act
HM Treasury: 2004	The orange book: management of risk- principles and concepts
HSE: 2001	Marine risk assessment
HSE: 2006a	Five steps to risk assessment
HSE: 2006b	Guidance on risk assessment for offshore installations
INCOSE: 2007	Systems engineering handbook: a guide for system life cycle processes and activities
ISO 17776: 2000	Petroleum and natural gas industries- offshore production installations- guidelines on tools and techniques for hazard identification and risk assessment
ISO/DIS 31000: 2017	Risk management- guidelines
ISO/IEC 15288: 2008	Systems and software engineering- system life cycle processes
ISO/TS 16901: 2015	Guidance on performing risk assessment in the design of onshore LNG installations including the ship/shore interface
MIL-STD-882B: 1984	System safety program requirement
MIL-STD-882E: 2008	Department of Defense standard practice system safety
NASA/SP-2011-3422	Risk management handbook
ORR: 2015	Common safety method for risk evaluation and assessment
PD ISO Guide 73: 2009	Risk management- vocabulary
PD ISO/IEC Guide 73: 2002	Risk management-vocabulary- guidelines for use in standards
PD ISO/TR 16732-2: 2012	Fire safety engineering- fire risk assessment
PD ISO/TR 31004: 2013	Risk management- guidance for the implementation of ISO 31000
RSSB GE/GN8643: 2014	Guidance on risk evaluation and risk acceptance

APPENDIX 2: HRA APPROVAL LETTER



Health Research Authority

Ms Gulsum Kaya
University of Cambridge
CB2 1PZ

Email: hra.approval@nhs.net

11 November 2016

Dear Ms Kaya

Letter of HRA Approval

Study title:	Designing a systems-based risk assessment framework for safety improvements in hospitals
IRAS project ID:	211390
REC reference:	16/HRA/4955
Sponsor	Cambridge University Hospital NHS Foundation Trust and the University of Cambridge

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details

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and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The attached document *“After HRA Approval – guidance for sponsors and investigators”* gives detailed guidance on reporting expectations for studies with HRA Approval, including:

- Working with organisations hosting the research
- Registration of Research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics and is updated in the light of changes in reporting expectations or procedures.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at <http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/>.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please email the HRA at hra.approval@nhs.net. Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>

Your IRAS project ID is **211390**. Please quote this on all correspondence.

IRAS project ID	211390
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Yours sincerely

Natalie Wilson
Assessor

Email: hra.approval@nhs.net

*Copy to: Mr Stephen Kelleher, Cambridge University Hospitals NHS Foundation Trust,
Sponsor and Lead NHS R&D contact*

APPENDIX 3: LETTER OF ACCESS

Cambridge University Hospitals 
NHS Foundation Trust

Research and Development Department

Box 277
Addenbrooke's Hospital
Hills Road
Cambridge
CB2 0QQ

Miss Gulsum Kubra Kaya
PhD Student
Engineering Design Centre
University of Cambridge
Dept of Engineering
Trumpington Street
Cambridge
CB2 1PZ

R&D Manager: Stephen Kelleher
stephen.kelleher@addenbrookes.nhs.uk
HR Manager: Debbie Richards
01223 274660
deborah.richards@addenbrookes.nhs.uk
HR Advisor: Gayle Lindsay
01223 348496
gayle.lindsay@addenbrookes.nhs.uk

16th February 2015

Dear Miss Kaya

Letter of access for research – System Safety Assessment

This letter confirms your right of access to conduct research through Cambridge University Hospitals NHS Foundation Trust for the purpose and on the terms and conditions set out below. This right of access commences on **1st March 2015** and ends on **28th February 2018** unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project and you have provided the Trust's R&D department with written evidence that you have completed GCP training from an EU institution before you start your research.

The information supplied about your role in research at Cambridge University Hospitals NHS Foundation Trust has been reviewed and you do not require an honorary research contract with this NHS organisation. We are satisfied that such pre-engagement checks as we consider necessary have been carried out.

You are considered to be a legal visitor to Cambridge University Hospitals NHS Foundation Trust premises. You are not entitled to any form of payment or access to other benefits provided by this NHS organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through Cambridge University Hospitals NHS Foundation Trust, you will remain accountable to your place of work **University of Cambridge** but you are required to follow the reasonable instructions of **Carol Heesom-Duff** in this NHS organisation or those given on their behalf in relation to the terms of this right of access.

Innovation and excellence in health and care

Addenbrooke's Hospital | Rosie Hospital

NIHR – Cambridge Biomedical Research Centre | Academic Health Science Centre – Cambridge University Health Partners

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with Cambridge University Hospitals NHS Foundation Trust policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with Cambridge University Hospitals NHS Foundation Trust in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on Cambridge University Hospitals NHS Foundation Trust premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

If you have a health condition or disability which may affect your research role and which might require reasonable special adjustments to your role, if you have not already done so, you must notify your employer and the Trust's R&D HR Office prior to commencing your research role at the Trust.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. Personal identifiable data must be carried securely at all times and mobile devices must be encrypted. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (<https://www.gov.uk/government/publications/confidentiality-nhs-code-of-practice>) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution. Data controllers could also be fined for a breach of the Data Protection Act 1998. You must familiarise yourself with the Trust's Information Governance Code of Conduct.

You must keep confidential any information regarding the design, conduct or management or results of any research unless authorised in writing by the Trust to disclose it. You must acknowledge the Trust's contribution in any publication arising out of this Agreement.

Subject to any agreement with your employer to the contrary (e.g. as part of a multi-centre study), any Intellectual Property (IP) resulting from research carried out under this Agreement will be the property of the Trust and you will do all things necessary or desirable to give effect to the assignment of this IP.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we

reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. You must not undertake regulated activity if you are barred from such work. If you are barred from working with adults or children this letter of access is immediately terminated. Your employer will immediately withdraw you from undertaking this or any other regulated activity and you **MUST** stop undertaking any regulated activity immediately.

Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

Cambridge University Hospitals NHS Foundation Trust will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

INDUCTION AND MANDATORY TRAINING

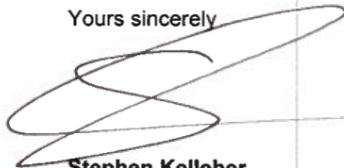
You are responsible for familiarising yourself with the Trust's policies and mandatory training courses such as Moving and Handling, Health and Safety, Fire Training etc and be aware of the responsibility to maintain a safe environment for patients, staff and visitors

Your host Manager will ensure that you receive a comprehensive Departmental Induction. She/he will also provide you with details of Corporate Induction, research specific induction and annual Mandatory Refresher Training.

If your letter of access is for more than 3 months, you must attend Corporate Induction. Where your letter of access is for more than 12 months, you must attend annual Mandatory Refresher Training.

If your current role or involvement in research changes, or any of the information provided in your Research Passport changes, you must inform your employer through their normal procedures. You must also inform your nominated manager in this NHS organisation.

Yours sincerely



Stephen Kelleher
R&D Manager, Cambridge University Hospitals NHS Foundation Trust

cc: Carol Heesom-Duff, Head of Patient Safety, Box 243
Jon Sanders, Administrator, Student Registry, University of Cambridge, 4 Mill Lane, Cambridge, CB2 1RZ

Enc: P6 form to confirm Letter of Access issued
ID Badge Form

APPENDIX 4: SUPPORTIVE RISK ASSESSMENT TOOLS

Audit: Aven (2011) defines risk management audit as a *“systematic, independent and documented process for obtaining evidence and evaluating it objectively in order to determine the extent to which the risk management framework, or any selected part of it, is adequate and effective”* (Aven 2011). Audits help to recognise actual practice as opposed to prescribed practice (Governance/ Risk Strategy and Policy, West Middlesex University Hospital NHS Trust).

Risk registers: Risk registers are defined as *“a database that holds the main record of all identified risks to the trust’s objectives and operations.”* (pg 7, Risk Management Strategy and Policy, Aintree University Hospital NHS Foundation Trust).

Incident reporting: Documenting adverse events, analysing and using that for learning and to improve current practice (Risk Management Strategy, Great Ormond Street Hospital for Children NHS Foundation Trust).

Heat map/ risk map/ risk matrix: A risk assessment tool to calculate the level of risk and determine acceptability of that risk (BSI 2010).

Root Cause Analysis: RCA identifies the root causes of a loss or error to identify corrective actions (BSI 2010).

Checklist: This is defined as *“lists of questions intended to prompt consideration of a full range of safety issues.”* (Mullai 2006).

Whistle blowing: It is described as raising a concern and drawing attention to it within the organisation or an outside body (Francis 2015; Chapman 2011).

Walk-around/ walkabout: Walk-around gives operational staff to the opportunity to discuss safety related issues with their managers directly (Vincent et al. 2013).

Horizon scanning: This is described as *“systematic activity designed to identify, as early as possible, indicators of changes in risk.”* (HM Treasury 2004).

Benchmarking: Benchmarking is defined as focusing on a specific event or process, comparing measures with common metrics and identifying opportunities for improvements (COSO 2012).

SWOT: This evaluates a business as a whole or a series of issues by determining strengths, weaknesses, opportunities and threats (Chapman 2011).

Brainstorming/ mind storming: This is a group discussion to trigger people's imaginations (BSI 2010).

PEST/PESTLE analysis: Its acronym stands for "*political, economic, social, technological, legal and environmental*", and it is used to analyse the impacts of these factors on an organisation (Chapman 2011).

Decision tree: This is a way of representing decision alternatives by determining uncertainties (BSI 2010).

Grapevine and intuition: This is explained as the recognition of risk management issues from ad hoc comments, hearsay or intuition (Risk Management Procedure, Colchester Hospital University NHS Foundation Trust).

Lean analysis: Lean is a systematic method to focus on reducing waste, synchronising work flows and managing variability in production flows (de Koning et al. 2006).

FMEA: This is a risk assessment technique to identify how systems, components or processes can fail (BSI 2010).

Bow-tie analysis: This helps to describe and analyse the pathways of a top event from causes to consequences (BSI 2010).

Event tree analysis: ETA is a graphical representation of sequences of events starting from an initiating event (BSI 2010).

Fault tree analysis: FTA is again a graphical representation to identify and analyse factors contributing to an undesired event (BSI 2010).

APPENDIX 5: INTERVIEW SCHEDULE

Interview Schedule

Research Title: Designing a systems-based risk assessment framework for safety improvements in hospitals

Interviewer: Gulsum Kubra Kaya

Introduction

Introduce myself:

My name is Kubra, and I am a researcher at the Engineering Department of the University of Cambridge.

Describe the research and its aim:

The research title is 'Designing a systems-based risk assessment framework for safety improvements in hospitals'. The research aims to extend people's understanding of proactive risk assessment practices in hospitals in order to ensure safety for all. To achieve this goal, your experiences in safety and risk assessment will help me understand current practice and design a new risk assessment approach.

Describe how long it will take

The interview will take approximately 45 minutes (maximum 1 hour).

Mention about the confidentiality issues

Data will be transcribed and stored anonymously and securely. After completion of the research all papers containing personal information will be disposed of through secured waste bins, all electronic data will be deleted from the university computers.

Questions for the Semi-structured Interviews

Rapport building

Can you please tell me a bit about your background and your role in the trust?

How long have you been working in the NHS?

Here, I would like to learn more about your experience on safety?

How frequently do you take part in a risk assessment?

If you have ever received any safety/risk management training, please can you tell what they are?

As the research aims to improve current risk assessment practice, it is essential to understand the practical application first. At this point your experiences will help me understand the practical application of risk assessment.

Understanding the current risk assessment practice

At this point, I am interested in learning from your actual experience of risk assessment. Here are some questions that I hope will help you in describing your experience:

Have you ever involved in a risk assessment?

- If yes, could you please share your experience with me?
 - What was the assessment for (e.g. response to an incident, to identify potential risks and to meet regulatory requirements)?
 - What were the risks (e.g. clinical, non-clinical)?
 - Was it an individual or team assessment?
 - How much time did you spend on the assessment?
 - Did you use any methods or software to conduct the assessment?
 - Did any documents guide you on the assessment (e.g. risk assessment procedure, HSE 5 steps to risk assessment and NPSA healthcare risk assessment made easy)? If yes, which documents are they?
 - How do you rank the likelihood and consequence of the risks (e.g. based on the guidance provided on the risk assessment policy)?
 - How do you prioritise risks (based on RPN; if same)?
 - How do you record and act on risks (using the risk register system; paper recording)?
 - Who would you ask for help on risk assessment (line manager)?
 - Who is responsible for conducting risk assessment in your working area? And what is his/her job title?
- In your experience, what were the key factors that lead a good risk assessment?
 - How much difference did your assessment made on the assessed issue?
 - What did the users think about the results of the assessment?
 - How could it have been done better?
- If no,
 - What would make you do a risk assessment?

Improvement of the risk assessment practice

Here, I would like to ask questions related to the potential improvements.

Do you think that risk matrix is to prioritise risks or to distribute responsibilities?

- Probe: Is it a useful tool?, Doing its job to prioritise?

On a scale of 1 to 10, how likely do you think that the following would help:

- Clarifying risk assessment terminology, process and scope? (providing definitions with examples, defining key points in the risk assessment process?)
- Guidance on the use of risk assessment methods?
- Explaining good risk assessment practice principles?

On a scale of 1 to 10, how likely do you use:

- A risk assessment guidance?

- An improved guidance more than current guidance?
- How do you learn from other conducted risk assessments that you were not involved?
- Probe: Any feedback mechanism?

Guidance on risk assessment

To understand what the current guidelines on risk assessment are, I would like to ask the questions of:

- What are the current key documents in your area which deal with risk assessment?
- Probe: Trusts Risk assessment procedure/policy? NPSA documents?
- How accessible is your trust's risk management or assessment procedure/strategy/policy?
- Probe: Any paper copy around your working area?, Online easily accessible?
- Are people keen to use these documents?
- Probe: Useful/needed?
- Do you think that these documents are sufficient enough to guide you?
- Probe: Clear process descriptions?, Clearly defined responsibilities?
- What else do you think should be included in a risk assessment guideline?
- Probe: A framework to highlight key points for the assessment?
 - Probe: A guidance of how to use risk assessment tools?

General questions on risk assessment

To understand your view on risk assessment, I would like to ask following questions:

In your view,

- What do you understand by risk assessment?
- Probe: definition and its process steps?
- Who do you think should involve in a risk assessment practice?
- Probe: Managers?, Senior staff?, Line managers?, Nurses?
- What are the benefits of conducting risk assessment?
- Probe: useful/needed?
- What do you think a good risk assessment would look like?
- Probe: a good software use?, use of PHA tools?, proactive approach?, systems thinking?
- What are the pitfalls in doing a risk assessment?
- Probe: Time-consuming?

Wrap-up Discussion

Is there anything else that you would like to add?

Closing

Thank you very much for participating in this interview. Your time is very much appreciated and your comments have been very helpful.

APPENDIX 6: INFORMATION SHEET

Interview Participant Information Sheet

Designing a systems-based risk assessment framework for safety improvements in hospitals

Before you decide to take part in this study it is important that you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. The researcher can be contacted at the address at the end of this document if you would like to discuss any aspect of this study. Take time to decide whether or not you wish to take part.

Purpose of the study

Safety in healthcare has been a major target for improvement over the last 20 years. Risk assessment is one of a number of approaches to ensure safety in hospital settings. Although risk assessment has already been adopted from other industries, there is still great potential to improve current practice by learning from the practical experience of NHS staff. This research project aims to improve risk assessment practice by developing a new risk assessment approach, through a literature review, and interviews, workshops and questionnaires with NHS staff. This study is a 3-year PhD research project, which will be completed towards the end of 2017.

Why have I been chosen?

This research focuses on hospital settings, and involves clinical and non-clinical staff, as both groups have valuable insights on current practice and problems in risk assessment. Both groups will also be will be potential users the designed approach.

Do I have to take part?

Taking part in any part of this research is entirely voluntary and participants can refuse to take part or withdraw at any point, without needing to give a reason.

What will happen to me if I take part?

An interview will take place, face to face in your trust, or by phone, and it will take approximately 45 minutes (maximum 1 hour). If you give permission, interviews will be audio recorded. Alternatively, the researcher will take notes. Data will be transcribed and stored anonymously and securely. After completion of the research all papers containing personal information will be disposed of through secured waste bins, all electronic data will be deleted from the university computers.

Are there possible disadvantages and/or risks in taking part?

There are no significant disadvantages or risks in taking part in this interview, other than the time it will take to collect your responses.

What are the possible benefits of taking part?

Your participation will help the researcher to develop a better understanding of risk assessment practice in hospitals. It may also help participants to think differently about safety risk assessment, which may in turn lead to further improvements in patient safety. Research findings will be shared if requested. Findings of the research may help participant to understand and apply effective risk assessment practices in their working environments.

What if there is a problem?

This study is sponsored by Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge and covered by University and NHS indemnity.

Who should I contact if I wish to make a complaint?

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during this study, you can do this through the NHS complaints procedure. In the first instance it may be helpful to contact the Patient Advice and Liaison Service (PALS) at your hospital.

Will my taking part in this project be kept confidential?

All data will be linked to individuals only by a code, with personal details kept in a locked file or secure computer with access only by the immediate research team.

What will happen to the results of the research project?

Results will be presented in the researcher's PhD thesis. Results may also be presented at conferences and written up in journals. If any individual data are presented, the data will be anonymous, without any means of identifying the individuals involved. Results can be shared with participants if they request.

Ethical review of the study

This project has received ethical approval from the Health Research Authority and Local R&Ds.

Contact for further information

Investigator Name: Gulsum Kubra Kaya

E-mail address: gkk21@cam.ac.uk

APPENDIX 7: INTERVIEW PARTICIPANT CONSENT FORM



Interview Participant Consent Form

Research title: Designing a systems-based risk assessment framework for safety improvements in hospitals

Researcher: Gulsum Kubra Kaya

Dear Participant,

Thank you very much for participating in this interview.

Your opinion and experience will be valuable in helping me to understand current risk assessment practice and to capture potential improvement areas. There will be six sets of questions that should take less than 1 hour in total.

Should you require any further information about this research, please contact me at the address below.

Please read the following statements and initial the box if you agree:

Initial Box

- | | |
|---|--------------------------|
| 1. I confirm that I have read and understand the Participant Information Sheet. | <input type="checkbox"/> |
| 2. I have had the opportunity to ask questions and have had them answered. | <input type="checkbox"/> |
| 3. I understand that all personal information will remain confidential and that all efforts will be made to ensure I cannot be identified (except as might be required by law). | <input type="checkbox"/> |
| 4. I agree that data gathered in this study may be stored anonymously and securely, and may be used for future research by Gulsum Kubra Kaya and by the research team. | <input type="checkbox"/> |
| 5. I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason. | <input type="checkbox"/> |
| 6. I agree to take part in this study. | <input type="checkbox"/> |
| 7. I agree to the audio recording of my interview with Gulsum Kubra Kaya. | <input type="checkbox"/> |
| 8. I would like to receive summary of the results at the end of the study (late 2017) via email. My email address is: _____ | <input type="checkbox"/> |

Participant _____ Signature _____ Date _____

Researcher _____ Signature _____ Date _____

Address for contact: Engineering Design Centre, Department of Engineering, University of Cambridge, Trumpington Street, Cambridge, CB2 1PZ **Email-address:** gkk21@cam.ac.uk

IRAS ID: 211390
Interview Participant Consent Form Version 1.2
16 September 2016

APPENDIX 8: QUESTIONNAIRE



Questionnaire: Understanding Risk Assessment Practice for Safety in Hospitals

This questionnaire aims to understand current safety risk assessment practice in hospitals as part of a PhD research project. I would be grateful if you could take about 5 minutes to complete this questionnaire. All the data from this will be stored and used anonymously for the research. Completing this questionnaire indicates permission for the researcher to use the data.

Risk assessment addresses the questions of “What can go wrong?”, “How bad is it?”, “How often does it happen?” and “Is there a need for action?”.

Q1. What is your job title? _____

Q2. What is your organisation type?

- ☐ NHS England acute care trust ☐ Mental health trust ☐ Non-NHS organisation
☐ Other (please specify) _____

Q3. Please tick if you have received safety training in any of the following areas? (Please select all that apply)

- ☐ Health and safety ☐ Risk officer ☐ Risk assessment ☐ Risk management
☐ Root cause analysis ☐ Other (specify) _____

Q4. In your experience, what is risk assessment used for? (Please select all that apply)

- ☐ Investigation of incidents ☐ Meeting requirements/responsibilities
☐ Assessing who is to blame ☐ Assessing potential harm
☐ Highlighting actions taken ☐ Registering risks ☐ Other (specify) _____

Q5. How frequently are you involved in a risk assessment?

- ☐ Daily ☐ Every few days ☐ Weekly ☐ Every few weeks ☐ Monthly
☐ Every few months ☐ Annually ☐ Never

Q6. In your experience, what are the main difficulties in doing risk assessments? (Please select that all apply)

- ☐ Lack of guidance ☐ Perceived value of the assessment
☐ Lack of support from above ☐ Insufficient knowledge/skills required
☐ Limited time availability ☐ Other (specify) _____

Q7. In your experience, how likely are you to find risk assessment easy to carry out?

- ☐ Not likely at all ☐ Not very likely ☐ Somewhat likely ☐ Very likely ☐ Extremely likely

Q8. In your experience, how sufficient do you find NHS risk assessment documents to guide you in this process?

- ☐ Very insufficient ☐ Somewhat insufficient ☐ Neither sufficient nor insufficient
☐ Somewhat sufficient ☐ Very sufficient

Q9. In your experience following an incident, how likely are you to conduct further related risk assessments?

- ☐ Not likely at all ☐ Not very likely ☐ Somewhat likely ☐ Very likely ☐ Extremely likely

Q10. In your experience, which methods and techniques do you use to assess risks? (Please select that all apply)

- | | | |
|---|--|--|
| <input type="checkbox"/> Root cause analysis | <input type="checkbox"/> Risk matrices | <input type="checkbox"/> Failure mode and effects analysis |
| <input type="checkbox"/> Barrier analysis | <input type="checkbox"/> Fault tree analysis | <input type="checkbox"/> Event tree analysis |
| <input type="checkbox"/> Human reliability analysis | <input type="checkbox"/> What-if (SWIFT) | <input type="checkbox"/> Hazard and operability analysis |
| <input type="checkbox"/> Software/ systems | <input type="checkbox"/> Other (specify) _____ | |

Q11. In your experience, how likely is it that your organisation will learn from a previous incident?

- ☐ Not likely at all ☐ Not very likely ☐ Somewhat likely ☐ Very likely ☐ Extremely likely

Q12. How long should each risk assessment take to complete?

- ☐ Up to 30 minutes ☐ 30 min- 1 hour ☐ 1-2 hours ☐ 2-3 hours ☐ Over 3 hours
☐ Other (specify) _____

Q13. Who do you think should be involved in a risk assessment? (Please select that all apply)

- | | | | |
|---|---|--|--|
| <input type="checkbox"/> Managers | <input type="checkbox"/> Risk leads/ officers | <input type="checkbox"/> Safety related units | <input type="checkbox"/> Senior clinical staff |
| <input type="checkbox"/> Clinical staff | <input type="checkbox"/> All | <input type="checkbox"/> Other (specify) _____ | |

Q14. What would encourage you most to be involved in a risk assessment? (Please select only one)

- ☐ Regulations ☐ Support from managers ☐ Understanding value of safety ☐ Training
☐ Recognition from managers ☐ Less workload ☐ Other (specify) _____

Q15. How likely do you think that a well designed framework could guide you to assess risks around you?

- ☐ Not likely at all ☐ Not very likely ☐ Somewhat likely ☐ Very likely ☐ Extremely likely

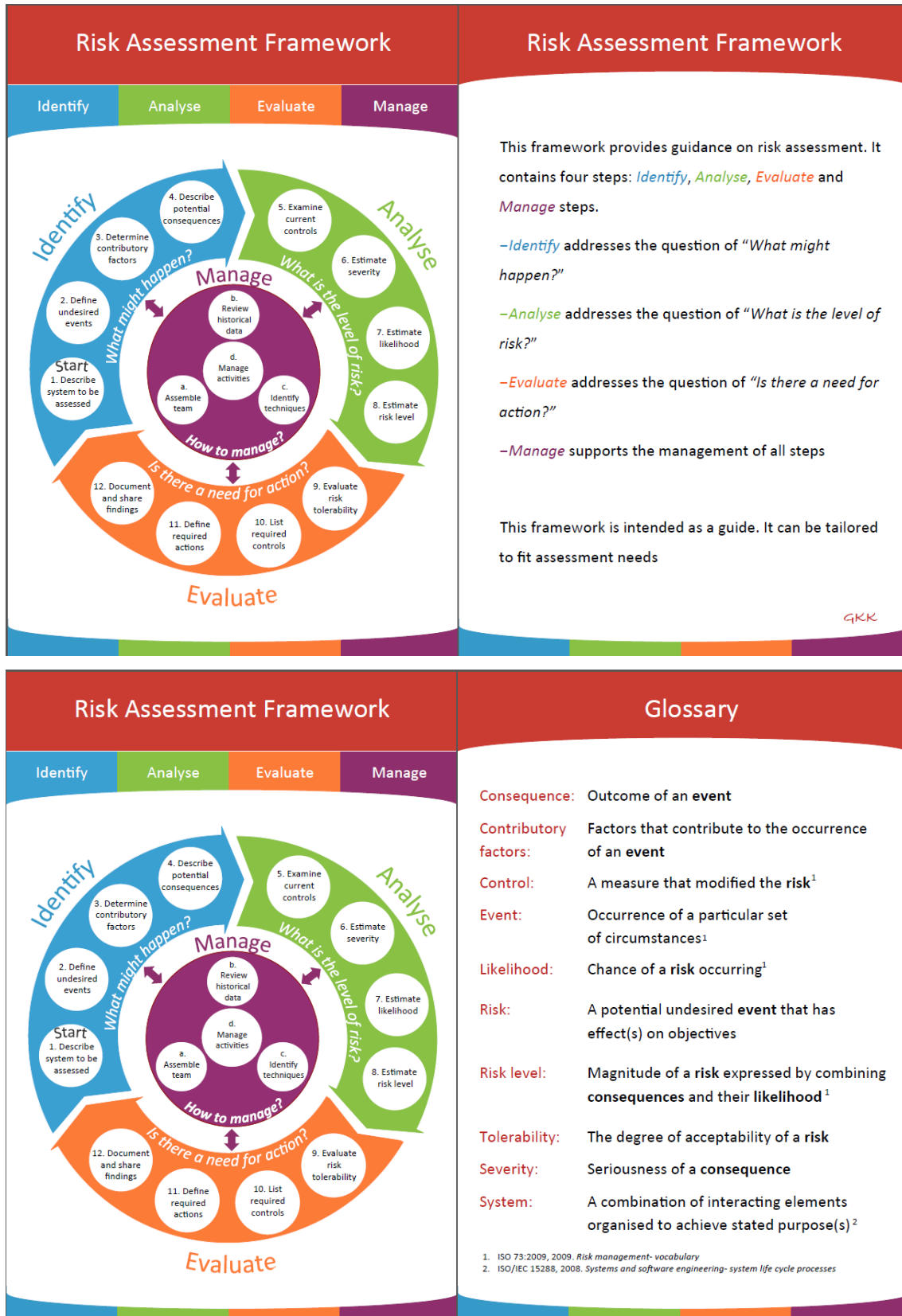
Q16. In your experience, what things should be considered to improve current risk assessment practice?

Please tick if you would like to

- ☐ Participate in further questionnaires or interviews
☐ Receive a summary of the results of this questionnaire
☐ My email address: _____

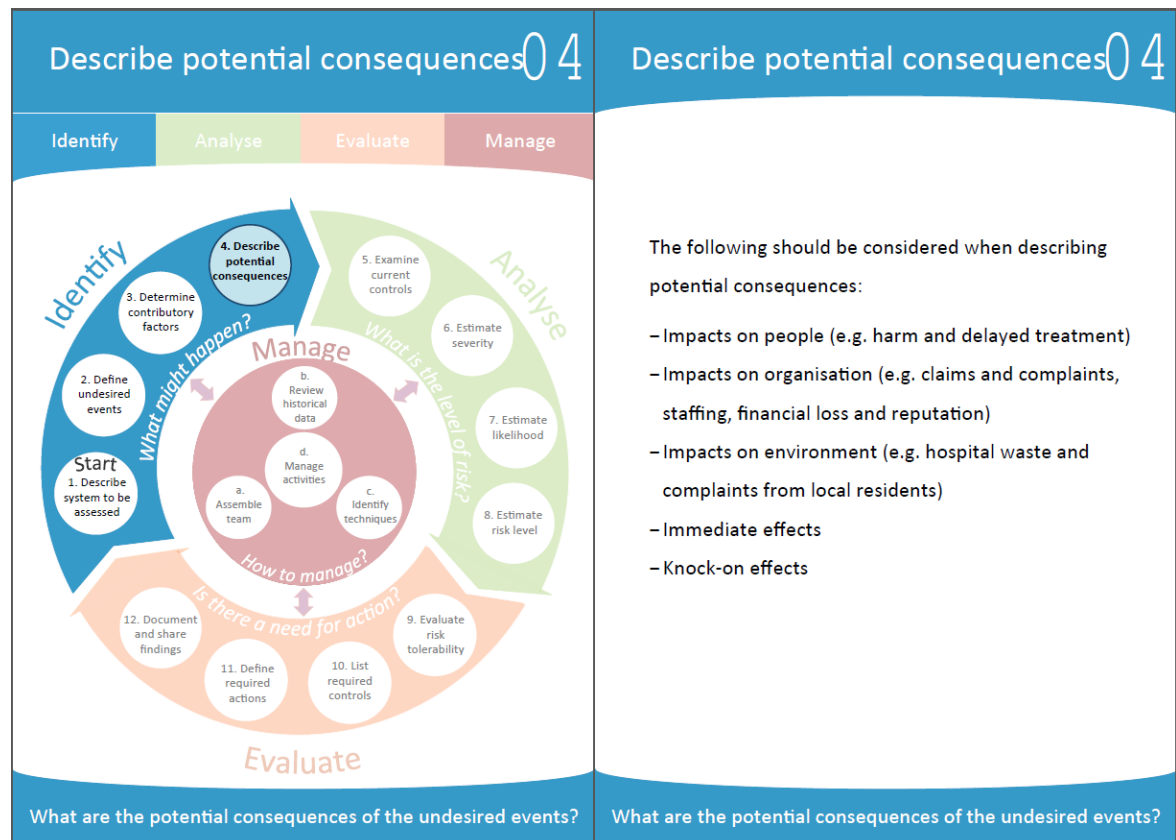
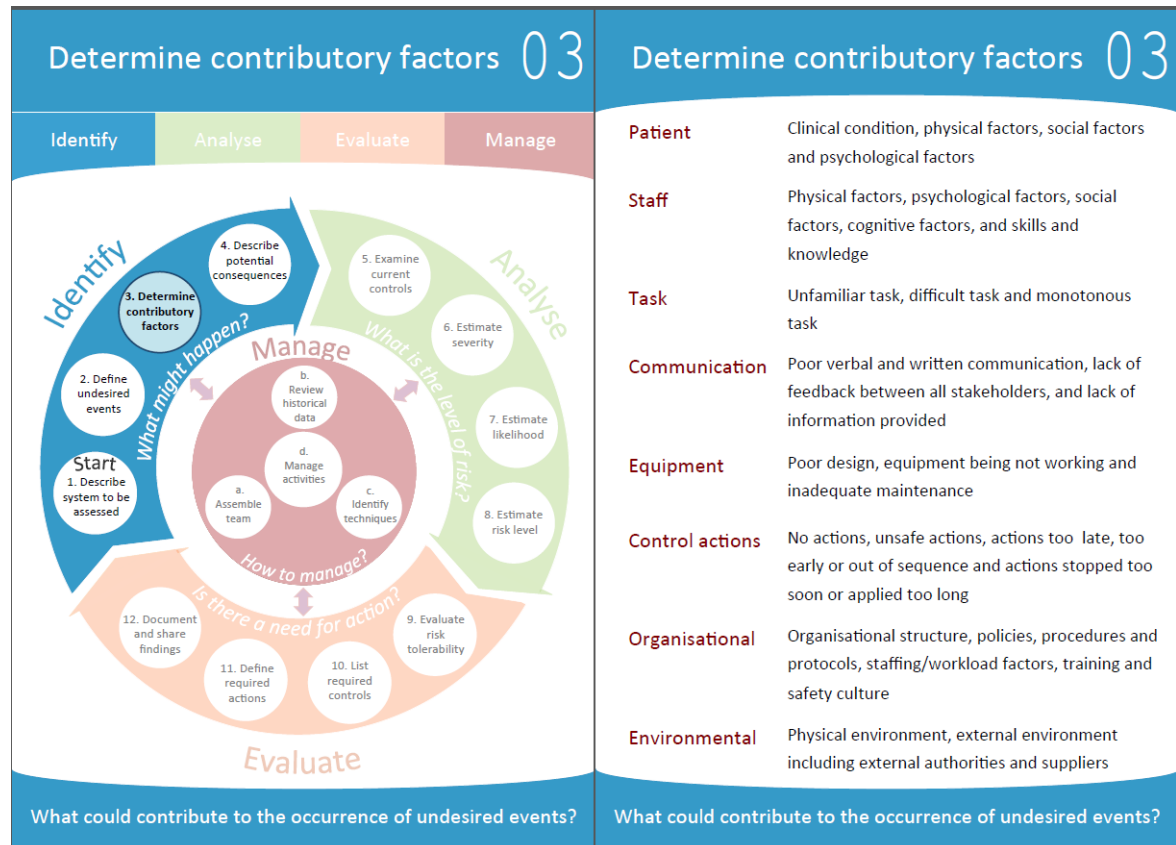
Thank you for your time and participation

APPENDIX 9: RAF EXPLANATION CARDS



Describe system to be assessed 01	Describe system to be assessed 01
<div data-label="Diagram"> </div> <p>What is being assessed and how does the system work?</p>	<p>The following factors should be considered to describe the system to be assessed:</p> <ul style="list-style-type: none"> – Assessment aim <i>What does the assessment aim to achieve?</i> – System elements <i>What are the parts of the system?</i> – Interactions of the system elements <i>What is the relationship between the system elements?</i> – System boundary <i>What is the scope of the system?</i> – System context <i>What is around the system to be assessed?</i> <p>Since the following steps will be built on this step, it is essential to describe the system well.</p> <p>What is being assessed and how does the system work?</p>

Define undesired events 02	Define undesired events 02
<div data-label="Diagram"> </div> <p>What could go wrong?</p>	<p>The following should be considered when defining undesired events:</p> <ul style="list-style-type: none"> – System description (i.e. aim, elements, interactions, boundary and context) – Extreme cases (e.g. fire) <p>Undesired events can be related to:</p> <ul style="list-style-type: none"> – Clinical practice (e.g. delayed discharge) – Organisation (e.g. bed shortage) – Health and safety (e.g. fire) – Information (e.g. breach of confidentiality) <p>What could go wrong?</p>



Examine current controls
05

Identify
Analyse
Evaluate
Manage

What are the current controls and how effective are they?

The following types of controls can be considered when examining current controls:

- Controls to prevent undesired events
- Controls to detect undesired events
- Controls to reduce the severity of consequences

The effectiveness of the current controls can be categorised as:

- Effective
- Neutral
- Ineffective

What are the current controls and how effective are they?

Estimate severity
06

Identify
Analyse
Evaluate
Manage

How severe are the described consequences?

Severity can be estimated through the use of:

- A rating (see below)
- Consequence descriptions for each impact area (e.g. harm, staffing and reputation)

Score	Rating	Descriptions for harm
1	Negligible	Minimal injury requiring no intervention
2	Minor	Minor injury requiring intervention
3	Moderate	Moderate injury increasing the length of hospital stay
4	Major	Major injury leading to incapacity
5	Catastrophic	Death

Source: NPSA, 2008. A risk matrix for risk managers

If a risk might result in different severity of consequences on the same consequence category (e.g. harm), the most worst-credible can be determined.

How severe are the described consequences?

Estimate likelihood

07

Identify
Analyse
Evaluate
Manage

What is the likelihood of occurrence of the consequences?

Estimate likelihood

07

Likelihood of occurrence can be estimated through the use of:

- A rating (see below)
- Frequency descriptions to be used for continuous operations
- Probability descriptions to be used for one-off projects

Score	Rating	Frequency Descriptions	Probability Descriptions
1	Rare	Not expected to occur for years	<0.1 %
2	Unlikely	At least annually	0.1- 1 %
3	Possible	At least monthly	1- 10 %
4	Likely	At least weekly	10- 50 %
5	Almost certain	At least daily	>50 %

Source: NPSA, 2008. A risk matrix for risk managers

What is the likelihood of occurrence of the consequences?

Estimate risk level

08

Identify
Analyse
Evaluate
Manage

What is the level of risk?

Estimate risk level

08

Risk level is estimated by:

- Combining the likelihood and consequence of a risk

Risk levels can be categorised as:

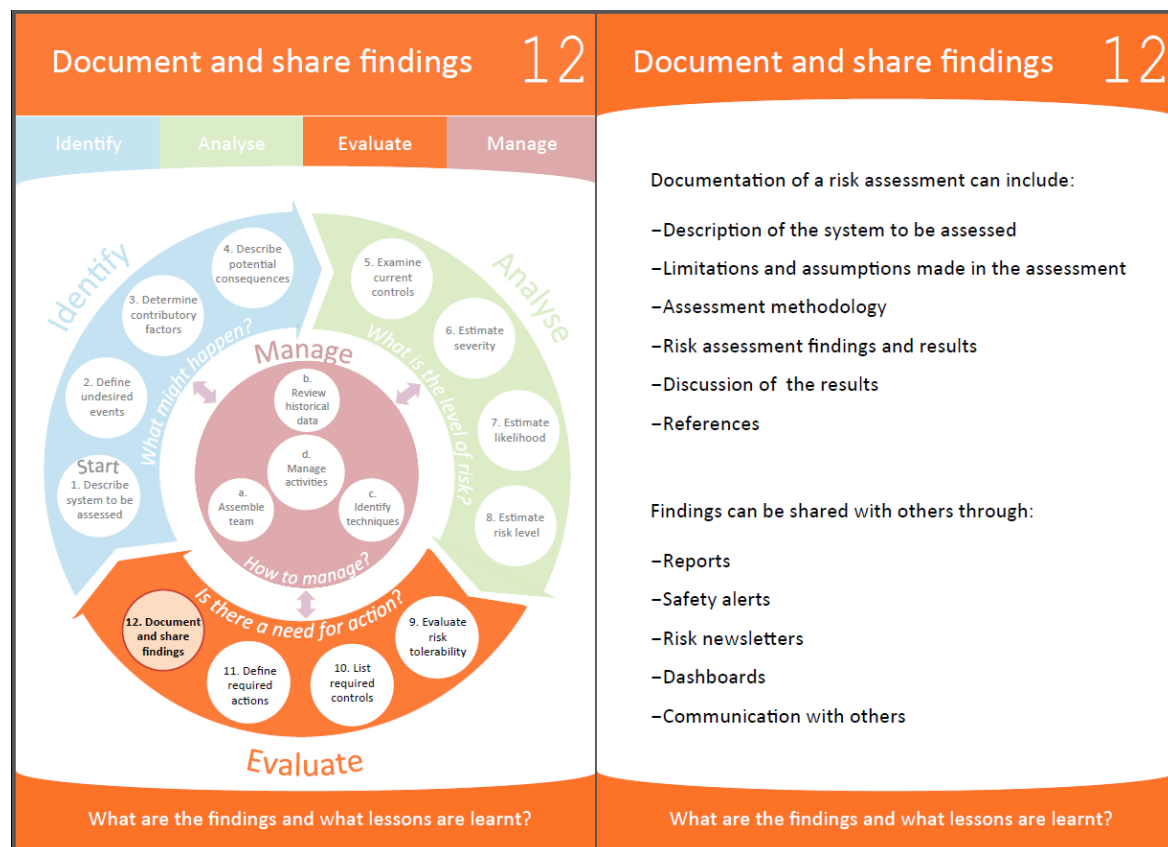
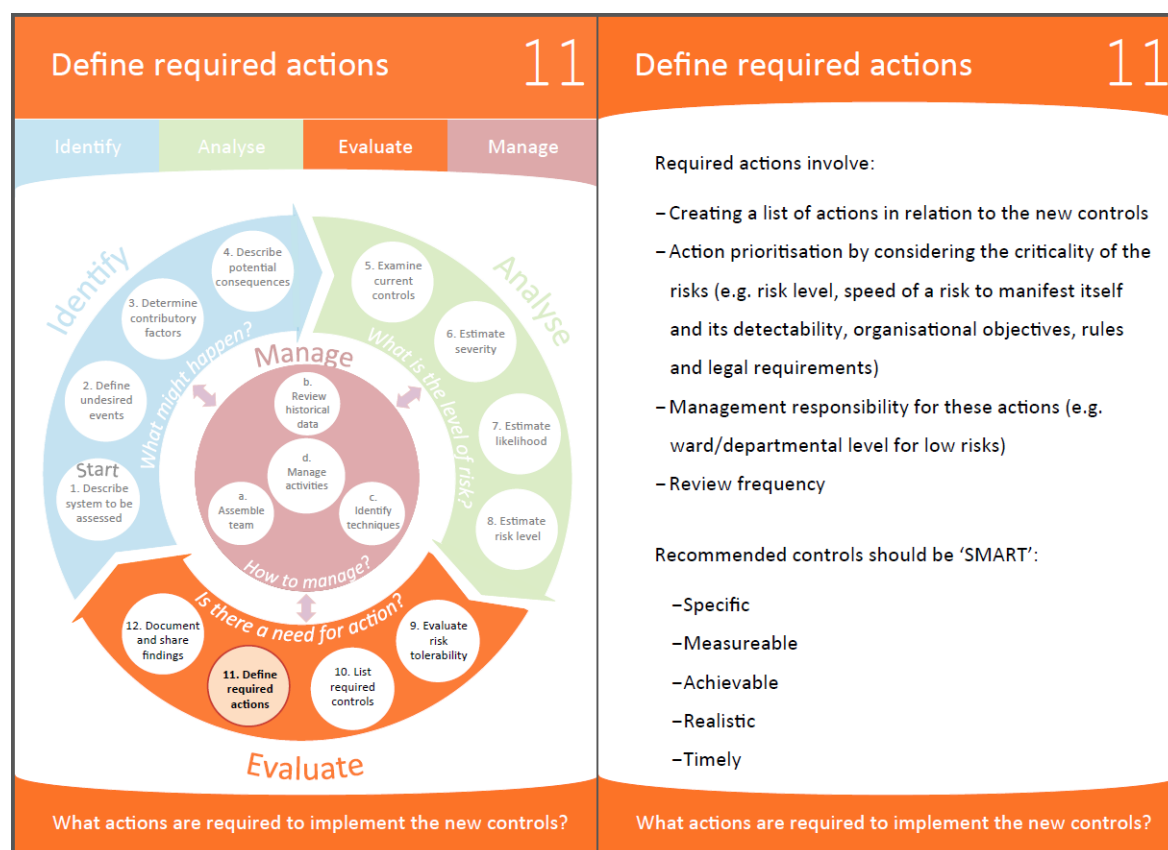
- Low (L)
- Medium (M)
- High (H)

		Severity				
		1 Negligible	2 Minor	3 Moderate	4 Major	5 Catastrophic
Likelihood	5 Almost certain	M	M	H	H	H
	4 Likely	L	M	M	H	H
	3 Possible	L	L	M	M	H
	2 Unlikely	L	L	L	M	M
	1 Rare	L	L	L	L	M

What is the level of risk?

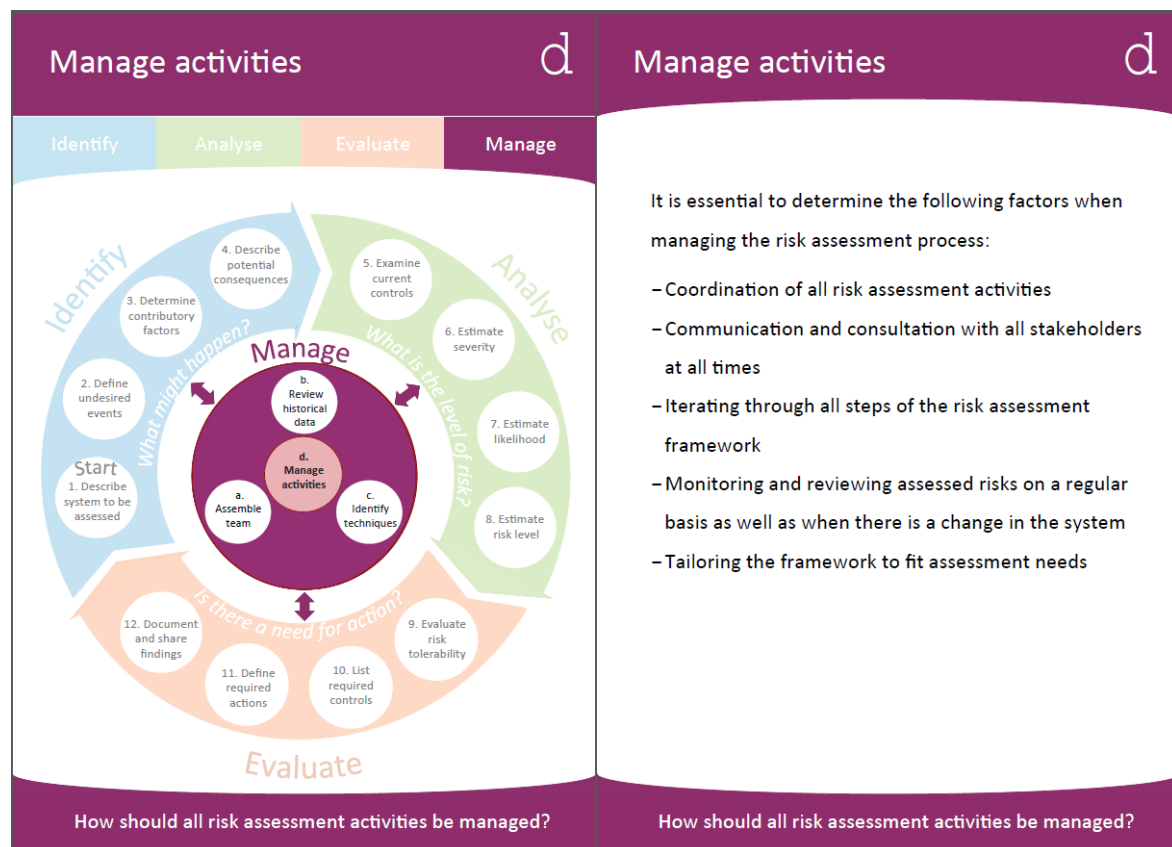
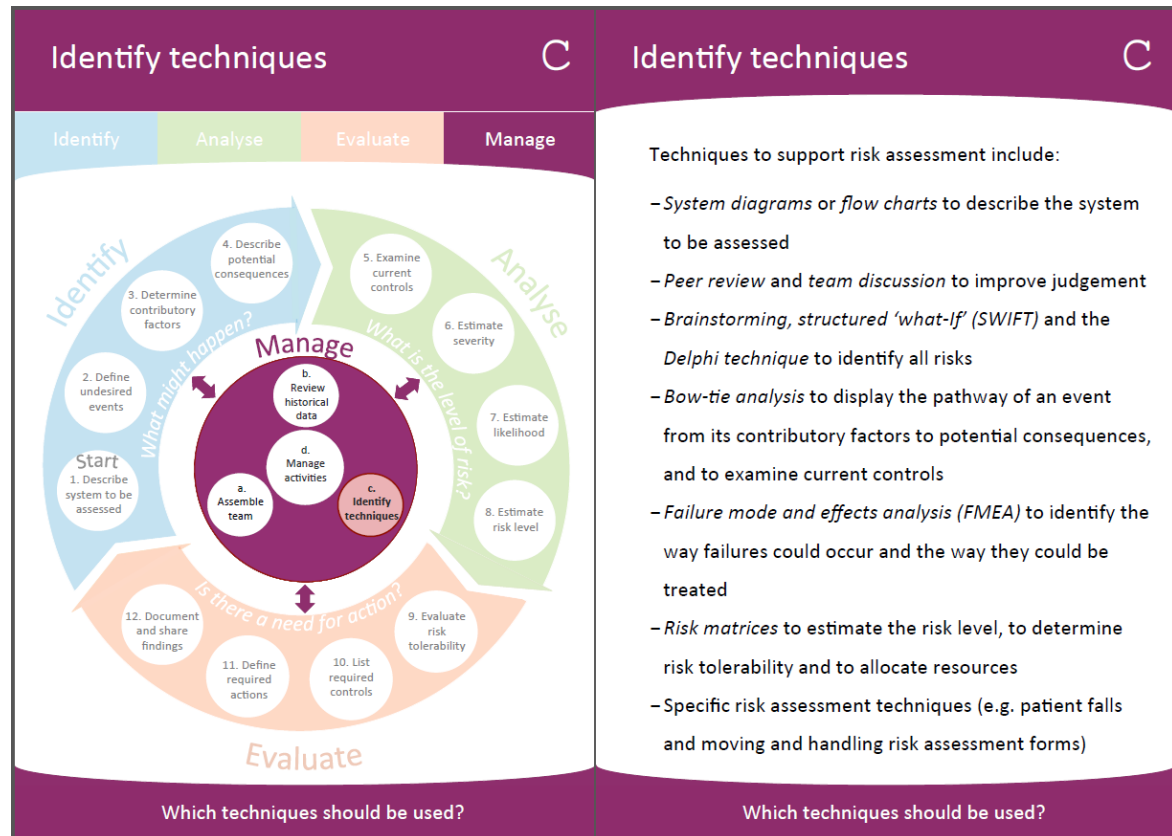
Evaluate risk tolerability 09	Evaluate risk tolerability 09
<p>How tolerable is the risk?</p>	<p>The following should be considered when deciding on the tolerability of a risk:</p> <ul style="list-style-type: none"> - Risk level <ul style="list-style-type: none"> Low risks: generally tolerable Medium risks: generally undesirable High risks: generally intolerable - Written rules (e.g. standards, policies and legal requirements) - Potential benefits of taking the risk <p>How tolerable is the risk?</p>

List required controls 10	List required controls 10
<p>What new controls are required to modify the risk?</p>	<p>The following should be considered to list new controls:</p> <ul style="list-style-type: none"> - Existing ineffective controls - Contributory factors - Controls to prevent undesired events - Controls to detect undesired events - Controls to reduce the severity of consequences <p>Be aware that new controls can raise new risks into the system, and some risks might not be eliminated.</p> <p>What new controls are required to modify the risk?</p>



Assemble team a	Assemble team a
<p>Who should be in the assessment team?</p>	<p>An ideal team should involve at least:</p> <ul style="list-style-type: none"> – A facilitator who has experience in risk assessment – A multidisciplinary group of experts on the system to be assessed <p>It might also be helpful to have:</p> <ul style="list-style-type: none"> – Somebody who is not directly involved in the system to be assessed <p>Be aware if a team assessment is not appropriate, peer reviewing is recommended to minimise subjectivity of the assessment.</p> <p>Who should be in the assessment team?</p>

Review historical data b	Review historical data b
<p>What can be learnt from historical data?</p>	<p>The following documents and data can be used to provide insights from existing data:</p> <ul style="list-style-type: none"> – Incident reports – Patient complaints and claims – Registered risks – Quality and performance reports – Safety alerts – Audit reports – Reports from external authorities – Academic literature <p>What can be learnt from historical data?</p>



APPENDIX 10: CASE STUDY RESULTS

Risk Assessment Form (Example)										
Assessor: G K Kaya		Ward/Department: Risk Management/ EDC			Date assessed: 01/08/17			Assessment no: 001		
<p>1. Describe system to be assessed (aim, elements, interactions, boundary, context)</p> <p>Aim: To identify all risks in relation to the patient's accommodation in the new single-bed patient rooms</p> <p>Elements: Physical elements include patient bed, over-bed table, bedside table, 2 chairs, wardrobe, TV, sink, light, bin, hand hygiene dispensing, floor, nurse call button and sphygmomanometer; stakeholders include patient, nurse, physician, doctor, physiotherapist, dietitian, speech and language therapist, hospital manager, suppliers and so on; activities involve patient transportation from bed to wheelchair, patients being checked, patient being slept and so on.</p> <p>Interactions: Communication between stakeholders and activities</p> <p>Boundary: Consideration of patient safety related risks in the new single-bed patient rooms</p> <p>Context: Patient's treatment delivery process, national standards for a single-bed patient rooms and hospitals care delivery process.</p>										
2. Define undesired events	3. Determine contributory factors	4. Describe potential consequences	5. Examine current controls	6. Estimate Severity	7. Estimate likelihood	8. Estimate risk level	9. Evaluate risk tolerability	10. List required controls	11. Define required actions	
1. Patient falls off the bed	Patient's old age, weight and clinical conditions, inadequate bed rails, room size	1.1 Minor cuts 1.2 Grazes 1.3 Hip fractures 1.4 Death 1.5 Patient Loss of confidence 1.6 Formal complaint	Soft floor surface (neutral) Nurse checking patient (neutral) Nurse call button (neutral)	1 2 4 5 3	3 3 1 1 3	3 Low 6 Low 4 Low 5 Medium 9 Medium	Tolerable Tolerable Tolerable Undesirable Undesirable	Replacement of the bed rails Decreasing the height of bed for vulnerable patients	Management should open a request to purchase bed rails; review after 6 months Nurses should adjust the height of the bed when necessary	
2. Patient suicide	Patients psychological condition, unsafe actions and untrained staff	2.1 Patient's serious injury 2.2 Patient's death 2.3 Patient claims from relatives	Building friendly communication with (neutral) Suicide risk assessment (effective)	4 5 3 2	1 1 1 1	1 Low 5 Medium 3 Low 2 Low	*Undesirable *Intolerable Tolerable Tolerable	Training staff on communication Removing sharp items if patient is assigned to have a risk of suicide	Management and training team should add communication topic into their induction training course; review after 6 months Nursing staff should assess the risk of suicide for each patient, and take appropriate actions immediately	
3. Fire in the room	Physical environment, smoking detector, building insulation material, lack of staff training, fire extinguisher	3.1 Multiple deaths 3.2 Multiple serious injuries	Fire safety training during inductions (effective) Fire safety regulations (neutral)	5 5	1 1	5 Medium 5 Medium	*Intolerable *Intolerable	Maintenance for the smoking detectors and alarm system Checking the expiry dates for the fire extinguisher Having fire evacuation drills	Management should arrange a contractor to have the relevant checks from time to time; review after a month Health and safety officers should test fire alarm weekly Risk management and health and safety officers should organise a fire evacuation drill each year	

4. Bed wetting	Patient's physical and clinical conditions, staff workload, staff late response to the patient's call and lack of controls	4.1 Low patient morale	Nurse call button (neutral) Extra clothes (neutral)	3	2	6 Low	Tolerable	Bed wetting alarm system Assisting patient to go to toilet during night	NA (tolerable)
5. Missing to provide treatment needs	Nursing staff workload, inexperienced staff, poor communication and problems with electronic patient record system	5.1 Minor harm 5.2 Treatment delay (1 day) 5.3 Informal complaint	Electronic patient records (effective)	1 1 2	2 2 2	2 Low 2 Low 4 Low	Tolerable	Double checking with patient and nursing staff Informing patient when something goes wrong	NA (tolerable)
6. Wrong needs are provided	Staff workload and poor communication during handover process	6.1 Minor harm 6.2 Patient confusion 6.3 Informal complaints	Electronic patient records system (effective)	1 3 2	2 2 2	2 Low 6 Low 4 Low	Tolerable	Double check with patient and other nursing staff Informing patient about the treatment at all time	NA (tolerable)
7. Patient does not take his/her medication	Patient memory and confusion, patient's clinical condition and staff tiredness, lack of control, and poor handover	7.1 Minor harm 7.2 Moderate harm 7.3 Staff low morale 7.4 Formal complaints	Electronic patient record system (effective) Reminding system (effective)	1 1 3 3	2 1 1 1	2 Low 1 Low 3 Low 3 Low	Tolerable	Double checking manual and electronic patient record Waiting for patient to take the medicine before leaving the room Measuring and controlling staff tiredness	NA (tolerable)
8. Patient falls off while being moved from a bed to a wheelchair	Patients old age, weight, osteoporosis, staff lack of expertise on moving patient, staff tiredness, lack of communication, old aged equipment	8.1 Bruises and grazes 8.2 Patient loss of confidence 8.3 Formal complaint	Guidance for moving and handling patients (effective) Having two carers (effective)	2 3 3	2 2 2	4 Low 6 Low 6 Low	*Undesirable	Training staff on moving and handling patients Having extra checks prior to the moving	Risk management department should update their training programme on moving and handling and preparing a verbal checklist (review after 6 months)
9. Patient falls on floor	Slippery floors, patient faints, feeling dizzy, low mobility, weight, staff tiredness and room design	9.1 Bruises and grazes 9.2 Head injury 9.3 Patient loss of confidence 9.4 Formal complaint 9.5 Delay on treatment	Assistance with 2 staff (effective) Wet floor signs (effective)	2 4 2 3 3	2 1 2 2 1	4 Low 4 Low 4 Low 6 Low 3 Low	*Undesirable	Special shoes for using toilet and bathroom Better design of the bathroom and toilet Special bracelet for vulnerable patients to be watched by all staff	Project management should arrange contractors and suppliers (review after 6 months)

10. Patient changes his/her position inappropriately	Patient's clinical conditions, patient being inappropriately positioned earlier, breakfast table inappropriately positioned, patient's inability to reach things	10.1 Muscle pain	Assisting to the patient to change his/her position (effective) Adjusting the positioning of breakfast table for the patient (effective) Nurse call button (neutral)	2	3	6 Low	Tolerable	NA (necessary controls are in place)	NA (tolerable)
11. Patient slides out of wheelchair	Patient's physical and clinical conditions, old equipment	11.1 Bruises 11.2 Open wounds 11.3 Increase risk of pressure ulcer 11.4 Treatment delay 11.5 Increased staff manual handling risk 11.6 Formal complaints	Guidance for moving and handling patients (effective) Nurse call button (neutral)	1 2 4 2 2 3	3 2 2 3 3 3	3 Low 4 Low 8 Medium 6 Low Low Medium	Undesirable	Training staff on moving and handling patients Informing patient for the use of wheelchair Replacing the seating material with a non-slip material	Relevant staff should be trained by risk leads and project management should contact to different suppliers for price proposal, and Health and Safety unit should involve the material selection and testing (review in 6 months)
12. Patient is disturbed with the outside noise	Man working outside, visitors and poor wall insulation	12.1 Patient discomfort in the room	Fixed visiting time restriction (effective)	1	1	1 Low	Tolerable	NA (risk is accepted)	NA (tolerable)
13. Patient is not being checked by nurse	Staff workload, staff confusion, poor communication, staff urgent cases and poor handover	13.1 No harm 13.2 Patient treatment delay 13.3 Patient discomfort	Scheduling patient visiting times (effective)	1 2 1	2 1 1	2 Low 2 Low 1 Low	Tolerable	Scheduling all staff activities daily Communicating with other staff at all time Having a patient reminder system	NA (tolerable)
14. Patient missed to practice activities learnt in therapy	Patient being too tired, patient having pain, patient not being well and staff workload	14.1 Treatment delay	Patient control (effective)	1	1	1 Low	Tolerable	NA (necessary controls are in place)	NA (tolerable)
15. Patient is malpracticed activities learnt in therapy	Patient's mobility, poor communication between staff and patient, and patient's confusion	15.1 Treatment delay 15.2 Muscle pain 15.3 Serious injury 15.4 Patient low morale	Having careers to help practice (effective)	1 2 4 3	1 2 1 2	1 Low 4 Low 4 Low 6 Low	*Undesirable	Documenting patient's practice activities Checking patient's records before helping practicing	All career staff should be trained by head of nursing review in 6 months

16. Patient's meal does not meet patient's dietary	Miscommunication between patient and rehab staff or between rehab staff and catering staff and wrong entrance of patient information to the electronic record system	16.1 Allergic reaction 16.2 Triggering patient's disease 16.3 Stomach pain	Electronic patient record system (effective) Checking with patient prior to the meal delivery (effective)	3 3 2	2 2 3	6 Low 6 Low 6 Low	Tolerable	NA (effective controls are in place)	NA (tolerable)
17. Patient feels discomfort in the bed	Patient weight, untrained staff, and slippery bed material	17.1 Bruises 17.2 Informal complaint	Staff training on positioning patients (effective) Checking patients time to time (effective)	2 2	4 3	8 Medium 6 Low	Undesirable Tolerable	Patient's confirmation on their comfort Using different material beds for vulnerable patients	Head of nursing updates the training programme and all staff should be trained, and finance and medical devices staff should consider upgrading bed mattresses review in 6 months
18. Patient is being too often checked by nurse	Patient's clinical condition, poor communication between staff and patient's requests	18.1 Patient's interrupted sleep	No control in place	2	2	4 Low	Tolerable	Adjusting staff responsibilities	NA (tolerable)
19. Patient ended his/her treatment	Patient's financial situation, patient's psychological and clinical conditions, patient's relatives concerns, and patient's social life factors	19.1 Long term treatment delay 19.2 Hospital's customer loss	Signing contract with patient before starting the treatment (effective)	4	1	4 Low	*Undesirable	Psychological support to patients Motivating patients with their progress Financial check prior to patient admission	Finance department should update their policy on patient admission, review in 6 months
20. Flood	External environment, natural conditions, and building design and structure material	20.1 Multiple injuries 20.2 Service interruption 20.3 Major financial loss 20.4 Damage to multiple equipments	Following building regulations (neutral)	5 4 3 3	1 1 1 1	5 Low 4 Low 3 Low 3 Low	*Undesirable	Training staff on natural disaster scenarios	Risk management should alter corporate induction training by adding natural disaster risk management section, review in 6 months